BlueCross BlueShield of Alabama

Name of Policy:
Minimally Invasive Lumbar Interbody Fusion

Policy #: 182
Category: Surgery

Latest Review Date: November 2013
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

A variety of minimally invasive/minimal access procedures are being investigated to perform interbody fusion, with the intent of limiting iatrogenic damage to muscular, ligamentous, neural, and vascular structures. Minimally invasive techniques are being studied for anterior lumbar fusion (ALIF), posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), lateral interbody fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF]), and para-axial interbody fusion (AxiaLIF).

Interbody fusion of the lumbar spine can be approached from an anterior, lateral, or posterior direction. Anterior or posterior lumbar interbody fusion (ALIF/PLIF) are traditionally performed with an open approach (long incision with wide retraction of the musculature), but can also be performed through minimally invasive/minimal access procedures. Procedures described as minimally invasive range from percutaneous techniques to minimal open access approaches that decrease the size of the incision and reduce muscle retraction. For example, minimally invasive/minimal access PLIF uses tubular retractors (e.g., METRx™, Luxor™) to allow access and open visualization of the surgical area. (PLIF is differentiated from instrumented or noninstrumented posterolateral intertransverse fusion, which fuses the transverse processes alone). Additional minimally invasive approaches that use specialized retractors are lateral transpsoas interbody fusion (LTIF), lateral interbody fusion (e.g., XLIF, DLIF), and transforaminal interbody fusion (TLIF). An axial approach (AxiaLIF), which is performed perpendicular to the long axis of the spine with access through the sacrum, is also being investigated.

Interbody fusion surgeries may also include decompression of the spinal canal, use of interbody cages, bone grafts and osteoinductive agents (e.g., recombinant human bone morphogenetic protein), and insertion of pedicle screws and rods to increase stability of the spine. Minimally invasive procedures may include percutaneous placement of pedicle screws and rods and/or use of bone morphogenetic protein in place of autograft bone harvested from the iliac crest.

Open and Minimally Invasive (MI) Approaches to Lumbar Interbody Fusion (LIF)

Procedure	Access	Approach	Visualization
Anterior (ALIF)	Open, MI, or laparoscopic	Transperitoneal or retroperitoneal	Direct, endoscopic or laparoscopic with fluoroscopic guidance
Posterior (PLIF)	Open or MI	Incision centered over spine with laminectomy/laminotomy and retraction of nerve	Direct, endoscopic or microscopic, with fluoroscopic guidance
Transforaminal (TLIF)	Open or MI	Offset from spine, through the intervertebral	Direct, endoscopic or microscopic,

		foramen via unilateral facetectomy	with fluoroscopic guidance
Lateral Extreme lateral (XLIF) Direct lateral (DLIF)	MI	Retroperitoneal through transpsoas	Direct, with neurologic monitoring and fluoroscopic guidance
Para-axial (AxiaLIF®)	MI	Small incision via the pre-sacral space	Indirect, percutaneous, fluoroscopic guidance

Anterior Lumbar Interbody Fusion (ALIF)
Anterior access provides direct visualization of the disc space, potentially allowing a more complete discectomy and better fusion than lateral or posterior approaches. An anterior approach avoids trauma to the paraspinal musculature, epidural scarring, traction on nerve roots, and dural tears. However, the retraction of the great vessels, peritoneal contents, and superior hypogastric sympathetic plexus with a peritoneal or retroperitoneal approach place these structures at risk of iatrogenic injury. Access to the posterior space for the treatment of nerve compression is also limited. Laparoscopic ALIF has also been investigated.

Posterior Lumbar Interbody Fusion (PLIF)
PLIF can be performed through either a traditional open procedure with a midline incision or with a minimally invasive approach using bilateral paramedian incisions. In the open procedure, the midline muscle attachments are divided along the central incision to facilitate wide muscle retraction and laminectomy. In minimally invasive PLIF, tubular retractors may be used to open smaller central bilateral working channels to access the pedicles and foramen. Minimally invasive PLIF typically involves partial laminotomies and facetectomies. The decompression allows treatment of spinal canal pathology (e.g., spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, hypertrophic ligamentum flavum) as well as stabilization of the spine through interbody fusion.

Transforaminal Lumbar Interbody Fusion (TLIF)
TLIF is differentiated from the more traditional bilateral PLIF by a unilateral approach to the disc space through the intervertebral foramen. In minimally invasive TLIF, a single incision about 2 to 3 cm in length is made approximately 3cm lateral to the midline. A tubular retractor is docked on the facet joint complex and a facetectomy with partial laminectomy is performed. Less dural retraction is needed with access through the foramen via unilateral facetectomy, and contralateral scar formation is eliminated. TLIF provides access to the posterior elements along with the intervertebral disc space.

Lateral Interbody Fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF])
Lateral interbody fusion uses specialized retractors in a minimally invasive, lateral approach to the anterior spine through the psoas. In comparison with ALIF, the lateral approach does not risk

injury to the peritoneum or great vessels. However, exposure to the spine may be more limited, and dissection of the psoas major places the nerves of the lumbar plexus at risk. Electromyographic monitoring and dissection predominantly within the anterior psoas major may be utilized to reduce the risk of nerve root injury. These various factors decrease the ability to perform a complete discectomy and address pathology of the posterior elements.

Axial Lumbar Interbody Fusion (AxiaLIF)
Axial lumbosacral interbody fusion (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.

The procedure for one level axial lumbosacral interbody fusion (axial LIF) is as follows: 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.

The AxiaLIF® and AxiaLIF II Level systems were developed by TranS1® and 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. The AxiaLIF® systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), 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 2, 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.

Policy:

Minimally invasive interbody fusion of the lumbar spine meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage using the following approaches:

- Anterior lumbar interbody fusion (ALIF), or
- Posterior lumbar interbody fusion (PLIF), or
- Transforaminal lumbar interbody fusion (TLIF)

All other minimally invasive procedures for lumbar interbody fusion do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**, including, but not limited to the following:

- Laparoscopic ALIF
- Axial anterior lumbar fusion (AxiaLIF)
- Lateral interbody fusion (e.g., XLIF, DLIF)

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Anterior Lumbar Interbody Fusion (ALIF)

In a 2005 review of the literature on laparoscopic ALIF, Inamasu and Guiot identified 19 studies which described the outcome of a L5-S1 laparoscopic ALIF, nine studies which described the outcome of the L4-L5 laparoscopic ALIF, and eight studies which described the outcome of a two-level laparoscopic ALIF. The review concluded that there was no marked difference between laparoscopic ALIF and the open or mini-open ALIF in terms of short-term efficacy (operative time, blood loss, and length of hospital stay), but there was a higher incidence of complications. In addition, the conversion rate to open surgery was considered to be high. It was noted that at the time of the review article, some spine surgeons were abandoning the laparoscopic approach and switching to mini-open ALIF.

The largest trial on laparoscopic ALIF was a prospective multicenter (19 surgeons from 10 U.S. centers) investigational device exemption (FDA-regulated) trial, published in 1999, that compared short-term outcomes from laparoscopic fusion of the spine (240 consecutive patients) and open ALIF (earlier cohort of 591 similar patients). Inclusion criteria were painful degenerative disc disease consisting of disc space narrowing at one or two contiguous levels (L4-L5 and L5-S1). Single level fusion was performed in 215 patients using laparoscopy and in 305 patients using the open procedure; 2-level fusions were performed in 25 patients via laparoscopy and 286 patients with the open procedure. In all surgeries autologous bone graft from the iliac crest was used in conjunction with an interbody cage, and a general or vascular surgeon assisted with the surgery. In 25 (10%) of the laparoscopy patients, conversion to an open procedure was required due to bleeding (n=6), anatomic considerations (n=5), adhesions or scar tissue limiting

access to the spine (n=8); and technical difficulties in placing the threaded cage (n=6). The hospital stay was modestly shorter for the single-level laparoscopy group (3.3 vs. 4 days), but not for patients undergoing 2-level laparoscopy. Operative time was increased (201 vs. 142 minutes) for the single-level laparoscopic approach (243 minutes for the 25 cases converted to open). For 2-level laparoscopy, the procedure time was 146 minutes longer than for the open approach. The reoperation rate for single-level procedures was 4.7% in the laparoscopy group compared with 2.3% in the open group (not significantly different). Major complications (implant migration, great vessel damage, and pulmonary embolism) were significantly lower in the laparoscopy group (0% vs. 2%). Postoperative complications were similar in the two groups, with an occurrence of 14.1% in the open approach and 19.1% for the laparoscopic approach.

A prospective comparison of 50 consecutive patients (25 in each group) with disabling discogenic pain who underwent 1 or 2 level ALIF at L4-L5 with either a laparoscopic or mini-open approach was reported by Zdeblick and David in 2000. The reasons for assignment to the different procedures were not described. There was no difference between the laparoscopic and mini-open approaches in operating time (125 vs. 123 minutes), blood loss (50 cc vs. 55 cc), or length of hospital stay (1.4 vs. 1.3 days) for single-level fusion. For 2-level fusion, the operating time was increased for the laparoscopic procedure (185 vs. 160 minutes). There was a 20% rate of complications in the laparoscopic group (disc herniation, ureter injury, iliac vein laceration, transient retrograde ejaculation, deep vein thrombosis) compared with 4% in the mini-open group (ileus). Exposure was considered inadequate in the laparoscopic group, with only a single interbody cage placed in 16% of patients in the laparoscopic group. All patients in the mini-open group had two interbody cages placed. Due to reports of a potentially a higher rate of complications with laparoscopic ALIF, this procedure is considered investigational.

A retrospective comparison between a cohort of 48 consecutive patients with spondylolisthesis who underwent mini-open ALIF and 46 patients who underwent minimally invasive TLIF during the same period of time was reported by Kim et al in 2009. Patients had persistent radiculopathy, progressive neurologic deficits, and lower-back pain for more than 6 months. Both groups underwent percutaneous pedicle screw fixation, however, only the TLIF group had decompression with removal of the ligamentum flavum. The mean time to return to work was significantly shorter in the ALIF group (6.1 months) than in the TLIF group (10.9 months). At an average of 33 (ALIF) and 30 (TLIF) months follow-up, independent assessment showed successful radiological fusion in 94% of the ALIF group and 98% of the TLIF group. There was no significant difference in disc height, listhesis, or lordosis between the two groups. Clinical outcomes, measured by visual analog scores (VAS) for pain and the Oswestry disability index (ODI), were similar for the two groups.

In 2010, the same group of investigators reported minimum five- to seven-year follow-up of 63 patients from a cohort of 73 patients (86%) with isthmic spondylolisthesis who had undergone mini-open ALIF combined with percutaneous pedicle screw fixation. The patients had a mean age of 50.6 years (range of 19 – 77 years). The minimally invasive ALIF was performed with an abdominal retroperitoneal approach using a robotic arm retractor and endoscope-assisted ballooning. The mean operating time was 210 minutes and there was a mean blood loss of 135 mL. No blood transfusions were needed. There were six cases of complications from the ALIF procedure (three iliac vein injuries, two wound hematomas, and one deep vein thrombosis) and 6

cases of complications from the percutaneous pedicle screw/rod procedure (two breakages of cortical walls of the vertebral body, three malpositions of screws, and one transient thigh numbness). Twenty-six patients (36%) were reported to have excellent results, 43 (59%) had good results, three (4%) were reported to have had fair results, and one patient (1%) had a poor result. Sixty-three patients (86%) were available for follow-up at a mean 72 months after the procedure. From this cohort, 89% had a good to excellent outcome, 8% had a fair outcome, and 3% had a poor outcome.

Minimally Invasive Posterior Lumbar Interbody Fusion (PLIF)
The 2010 literature review update identified a number of studies on minimally invasive PLIF. Prospective comparative studies and larger retrospective comparisons are described below.

In 2007, Park and Ha reported minimum 12-month follow-up from a prospective cohort study that compared minimally invasive (n = 32) and open (n = 29) single-level PLIF. The choice of procedure was determined by the ability to pay for the minimally invasive approach, which was not covered by medical insurance in Korea during that time period (Oct 2003 – Oct 2004). Indications for surgery were segmental instability at the level of spinal stenosis, lumbar disc herniation, and low-grade spondylolisthesis. Patients who had previous spinal surgery or who needed multiple levels of decompression were excluded. In the minimally invasive group, microscopic visualization was used with the aid of tubular retractors (METRx-MD) that created a working channel through two small paramedian skin incisions. Percutaneous pedicle screw-rod fixation (Sextant system) of the motion segment was completed through the same incisions after removal of the tubular retractors. The preoperative diagnosis of the groups was comparable at baseline; there was a trend towards greater severity on the American Society of Anesthesiologists (ASA) score in the minimally invasive group (69% vs. 48% Class 2). Although surgical time increased from 149 to 192 minutes, all other intraoperative variables were improved by the minimally invasive procedure. These included mean intraoperative blood loss (433 vs. 738 mL), postoperative drainage (175 vs. 483 mL), days before ambulation (1.2 vs. 3.0) and days of hospital stay (5.3 vs. 10.8). Postoperative back pain was lower at all times after surgery, with a visual analog score (VAS) for pain of 2.1 versus 3.8 in the open group at the final (> 12 month) follow-up. Good to excellent results were obtained in 91% of the minimally invasive group and 90% of the traditional open group. Radiographic outcomes were similar in the two groups. The minimally invasive group had one case of screw malposition and one case of cage migration. The authors noted that there is a steep and prolonged learning curve for minimally invasive spine surgery, and prudent attention is needed to lower the risk of technical complications.

In 2010, Ghahreman et al reported a prospective study comparing minimally invasive versus open PLIF in 47 patients with spondylolisthesis and radicular pain that met inclusion criteria and agreed to participate in the study. The study was performed as part of a quality assurance audit with independent assessment of outcomes 12 months after treatment. Patients chose the minimally invasive or open procedure after explanation that the effectiveness of the traditional approach was known but involved more extensive surgery, while the outcomes of the new minimally invasive approach were unknown. For the minimally invasive approach, bilateral hemilaminectomies and facetectomies were performed through 3 cm paramedian incisions. The pedicle screws were placed with direct visualization down the tubular retractor. For all but three

patients in the minimally invasive group, the fusion was single-level. Generally, the two groups of patients were similar at baseline, there was a significant difference in the percent of patients with listhesis and a difference in baseline disc height; these were adjusted for in the statistical analysis. With the minimally invasive approach there were trends towards increased operating time (median of 220 vs. 203 minutes; p = 0.08), but decreased percentage of patients requiring transfusion (4% vs. 21%; p = 0.09). Radiological outcomes were similar in the two groups at 12-month follow-up, and only one patient who underwent the open procedure had failure of fusion. The patients who had the minimally invasive approach had a shorter time to independent mobility (median of two vs. four days) and a shorter hospital stay (median of 4 vs. 7 days). Clinical outcomes (e.g., back pain, leg pain, bodily pain, functioning) were similar for the two groups.

Kasis et al published a comparative study of a procedure they called limited exposure PLIF (a small central incision and use of bone marrow aspirate, n = 209 consecutive patients) and standard open PLIF (single surgeon, 114 historical controls) in 2009. All patients had chronic low back pain for a minimum of two years that was unresponsive to conservative treatment, had MRI evidence of disc degeneration, and an Oswestry disability index (ODI) > 30. The limited access procedure was performed with a smaller central incision and direct visualization. In the standard open procedure bone graft was harvested from the iliac crest; in the limited access procedure the laminectomy was partial and bone graft was obtained from the facetectomy and mixed with bone marrow aspirate from the iliac crest. All screws were inserted by direct vision. At baseline, and at six weeks, three months, and six months, then at six-month intervals thereafter, patients completed an internet-based self-assessment questionnaire (Global Patient Outcome System, GPOS) which included automatically assessed values for the ODI, short-form 36, and visual analog scores (VAS) for pain. The duration of follow-up averaged 6.4 years for the standard approach and 3.4 years for the limited access approach. Follow-up was available for 114 of 126 patients (90%) treated with the standard open approach and 209 of 223 patients (94%) undergoing limited access PLIF. Limited access was found to reduce the hospital stay from 4.0 days to 2.2 days and result in improved clinical outcomes at the latest follow-up. For example, the ODI improved by 22.5 points with the standard open approach and by 28.8 points with the limited access approach. VAS back pain improved from 6.4 to 2.7 with the standard approach and from 7.2 to 1.9 with limited access. VAS leg pain improved from 6.5 to 2.5 with the standard approach and from 6.3 to 1.2 with limited access. The limited access procedure was found to reduce bone graft donor site pain without increasing other adverse events. Although limited by the longer follow-up in the patients treated with the standard open access (i.e., confounded by the potential for adjacent level disease over time), these results do suggest that a limited access approach to PLIF does not result in poorer outcomes than a standard open procedure.

Other publications from the U.S. report the use of open and minimally invasive PLIF for different patient populations. For example, a retrospective comparative review by Bagan et al found that more procedures in their open cohort were revisions, and there was a higher prevalence of diabetes mellitus and hypertension in the open cohort. Another retrospective analysis reported that patients presenting with bilateral neurological symptoms were treated with open surgery, while those with unilateral symptoms were treated with minimally invasive PLIF. Although the complication profile is reported to be favorable with minimally invasive PLIF in

comparison with open PLIF, the different patient populations in these retrospective studies limits direct comparison of results.

Minimally Invasive Transforaminal Lumbar Interbody Fusion (TLIF)
A meta-analysis of minimally invasive and open TLIF, published in 2010, identified 23 studies (1028 patients) that met the study inclusion criteria. All patients in the studies presented with spondylolisthesis, herniated nucleus pulposus, stenosis, or other degenerative lumbar disease. The included studies were all considered Class III evidence (observational); no randomized controlled trials comparing minimally invasive and open TLIF were identified. The meta-analysis included 312 patients (eight studies) who underwent minimally invasive TLIF and 716 patients (16 studies) who underwent open TLIF. Mean clinical follow-up ranged from nine to 46 months. After adjustment for publication bias, the fusion rate for the minimally invasive procedure was 94%, compared to 91% for open TLIF. Use of structural allograft and bone morphogenetic protein (BMP) were more frequent in the minimally invasive (54% and 50%, respectively) than the open procedure (14% and 12%, respectively). The percentage of single-level fusions was higher in the minimally invasive than open TLIF (84% vs. 68%). Complication rates, after adjustment for publication bias, were 18% for open TLIF and 8% for minimally invasive TLIF. The type of complications reported included dural tear/cerebrospinal fluid leak (n=34), new onset radiculopathy (n=32), infection (n=16), and misplaced screws (n=14). Other clinical outcomes were not assessed in this meta-analysis due to variability in assessment tools and reporting. Given reports of symptomatic ectopic bone formation with off-label application of BMP in posterior and transforaminal interbody fusion, it is notable that BMP was used in as many as 84% of patients in the studies reviewed. As indicated by this meta-analysis, there are a number of publications describing the use of minimally invasive TLIF. Also identified in the 2010 literature update were prospective and retrospective cohort studies that compared outcomes from minimally invasive and open TLIF without the use of BMP; the largest of these comparative studies are described below.

A prospective pseudo-randomized study comparing minimally invasive and open TLIF in 62 patients was reported by Shunwu et al in 2010. Patients diagnosed with discogenic low back pain, intervertebral space stenosis with unilateral huge lumbar disc herniation, foraminal stenosis, separation of the posterior ring apophysis at the level of spinal stenosis, low-grade spondylolisthesis, or single segmental instability were assigned to the minimally invasive group (n=32) if admitted on even-numbered days or to the open group (n=30) if admitted on odd-numbered days. The two groups were generally similar at baseline and had comparable follow-up (92%). Following the minimally invasive unilateral or bilateral paravertebral incisions, tube retractors were expanded to provide an operative field diameter of 2.5 to 4.0 cm (pedicle to pedicle). Pedicle screws and rods were inserted percutaneously, and the pedicle screw and rod system was distracted to achieve distraction of the intervertebral space. Decompression was achieved by cutting the inferior portion of the lamina, hypertrophied articular processes, and ligamenta flava. Interbody cages and iliac crest bone graft were used for interbody fusion. The operative duration was slightly longer for the minimally invasive group (159 vs. 142 min), and intraoperative blood loss was slightly reduced (400 vs. 517 mL). Times to ambulation (3.2 days) and length of hospital stay (9.3 days) were reduced compared to patients who underwent the open procedure (5.4 and 12.5 days, respectively). At 24-month follow-up, radiographic outcomes were similar for the 2 groups. The ODI for the minimally invasive and open groups were 27.2

and 24.7, respectively. VAS for pain was 2.3 for the minimally invasive group and 3.2 for the open group. Complications were observed in six patients who underwent minimally invasive TLIF (including 2-screw malposition) and five patients who underwent the open procedure.

A prospective comparison of minimally invasive (n = 42) and open (n = 43) TLIF was reported by Wang et al in 2010. Eighty-five consecutive patients with single-level degenerative or isthmic spondylolisthesis were treated by different surgeons (one surgeon performed minimally invasive TLIF and the other performed open TLIF) at the same hospital during the same period of time. For the minimally invasive procedure a retractor system with a 3-cm incision was used for placement of autologous bone graft, obtained from the facetectomy, in conjunction with an interbody cage. Percutaneous pedicle screws were implanted with palpation and fluoroscopic guidance. Comparison of the minimally invasive with the open procedure showed similar operating time (156 vs. 145 minutes), reduced blood loss (264 vs. 673 mL) and less blood transfusion (0.12 vs. 1.47), but an increase in x-ray time (84 vs. 37 minutes). Hospital stay was reduced in the minimally invasive group (10.6 vs. 14.6 days). Follow-up at an average 26 months (range, 13-35 months) showed no difference in VAS or ODI between the two groups. Reported complications in the minimally invasive group were two small dural tears and two new radiculopathies that resolved with reoperation. In the open group, there were two dural tears and one pedicle screw malposition that required revision surgery. Each group had one case of nonunion without complaint of back pain.

In 2010, Villavicencio et al compared their first 76 consecutive patients undergoing minimally invasive TLIF with a matched cohort of 63 patients who had undergone open TLIF. Patients were matched based on diagnosis (painful degenerative disc disease, spondylolisthesis, and/or stenosis), number of spinal levels (75% of both groups had one level and 25% had two level), and history of previous lumbar surgery (28% of the minimally invasive group and 40% of the open group). All patients underwent placement of interbody structural allografts with locally harvested autograft. In some cases, cancellous bone substitute was utilized, and use of BMP was slightly, but not significantly, higher with the minimally invasive procedure (80% vs. 68% of cases). The operative time was similar for the two procedures (223 for minimally invasive and 215 for open); blood loss (163 vs. 367 mLs) and hospital stay (3.0 vs. 4.2 days) were reduced. The overall complication rate was similar in the two groups (31.6% vs. 31.7%), but there were more major complications in the minimally invasive group (18.4% vs. 9.5%). Six out of eight of the observed nerve injuries were noted to have occurred in the author's first 15 minimally invasive cases, indicating a steep learning curve for this procedure. The rate of minor complications, including cerebrospinal fluid leak and anemia, was higher for the open procedure (22.2% vs. 13.2% of patients). At a mean 38-months follow-up (range 26-52), radiographic fusion was considered successful in all patients. VAS improved from 7.4 to 3.4 for the group who underwent minimally invasive TLIF and from 8.0 to 3.2 for the open group; these scores were not statistically different.

Clinical outcomes from 25 matched pairs of patients were reported by Peng et al in 2009. The 25 patients were out of 29 who underwent minimally invasive TLIF and included the surgeon's learning cases; these were compared by retrospective review of patients matched based on age, sex, and level operated (reasons for excluding four patient pairs were not described). Indications for surgery were Grade 1 or 2 spondylolisthesis and degenerate discs presenting with mechanical

low back pain and radicular symptoms. Patients undergoing the minimally invasive TLIF had longer fluoroscopy time (105 vs. 35 sec) and longer surgery time (216 vs. 170 min), but a reduction in blood loss (150 vs. 681 mL) and need for transfusion (0 vs. 14%). Time to ambulation (1.4 vs. 3.0 days), length of hospitalization (4.0 vs. 6.7 days), VAS on discharge (1.7 vs. 2.8), and total morphine (17.4 vs. 35.7 mg) were also reduced compared to the standard open group. The complication rate for the minimally invasive patients (6.9%, from two iliac crest bone graft site infections) was lower than for patients who underwent open TLIF (13.8%, one atelectasis, two urinary tract infections, and one wound infection). Outcomes (prospectively collected with independent evaluation) at a minimum of 24 month follow-up showed no significant difference between groups in North American Spine Society (NASS) scores (back pain/disability and neurogenic symptoms), the ODI, or the SF-36. No significant differences were observed in fusion rates (80% of minimally invasive and 87% of open procedures achieved Grade 1 fusion).

Rouben et al assessed 49 month (range, 36 to 60 months) outcomes of single-level or 2-level minimally invasive TLIF in a retrospective review of prospectively collected data. To be included in the study, patients had to have preoperative and minimum three years postoperative ODI and VAS pain scores and imaging studies. Excluded from the study were patients with scoliosis >10 degrees, spondylolisthesis greater than Grade II, preoperative lumbar segment disease in excess of two levels, prior lumbar infection, failed lumbar fusion, or psychological factors preventing follow-up. All patients had failed a minimum three months of conservative medical management before surgery. A total of 169 patients met the study inclusion criteria with either isolated single-level (n=124) or 2-level (n=45) lumbar intervertebral segment pain. The primary diagnosis was degenerative spondylolisthesis (n=35), central herniated disc (n=41), central stenosis (n=9), Foraminal-lateral herniation of disc (n=53), Foraminal/lateral stenosis (n=12), or isolated degenerative disc or joint disease (n=19). The hospital stay averaged 15 hours and the median return to work time was eight weeks. Data collection, which included patient reported outcomes, was conducted preoperatively and at 3, 12 and 24 months, and then at yearly visits. Fusion rates (cages were filled with locally harvested autologous bone and off-label use of bone morphogenetic protein) were 96% at 1-year follow-up. The overall rate for repeat surgery was 14.2%, with the most common reason being removal of painful pedicle screws. At the last follow-up, 86% of patients reached a 20% clinical improvement in ODI. The average improvement in VAS pain scores was 31% at the initial follow-up, and was maintained at each subsequent follow-up. Patients with 2-level fusions improved similarly in both ODI and VAS scores as 1-level fusion patients (e.g., range of 66 to 77 at baseline and 26 to 30 at last follow-up. This study has an indeterminate potential for bias, due to the restrictive inclusion criteria (for a retrospective study) and lack of reporting of patients in the series who were lost to follow-up before three years.

Neal and Rosner studied the learning curve for minimally invasive TLIF for a single U.S. medical resident during his postgraduate year five. The resident performed 28 procedures with an attending surgeon present during a 19-month period. The accuracy of pedicle screw placement, as determined on postoperative CT scans, was 97% for the first 14 patients and 94% for the next 14 patients (the latter group of patients were believed to include more difficult cases). The three misplaced screws were not symptomatic and did not require revision. Excluding two cases with Grade III spondylolisthesis, the average operating time was 121

minutes for the first 13 cases and 105 minutes for the second group of cases. A plot of the operative time per level indicated that the operative time plateaued (i.e., time to learn the procedure) at about 15 cases. Additional studies are planned to evaluate a larger number of trainees and to assess the effect of the learning curve on long-term patient outcomes.

Lateral Interbody Fusion

The evidence on lateral interbody fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF]), as identified in the 2011 literature update, is limited. The majority of studies published to date are recently published small case series. Studies considered most relevant to this policy are described below.

In a 2009 report, Knight et al compared complications from a series of 58 patients who underwent XLIF or DLIF (1- to 3-level) with a historical cohort of patients who underwent open posterolateral lumbar fusion. Thirteen patients (22.4%) experienced a mild or major complication. Nine of the complications were approach-related (2 L4 nerve root injuries, six cases of meralgia paresthetica, and 1 case of significant psoas muscle spasm). In four additional cases, the procedure was aborted because of concerns about nerve proximity. Compared with the historical cohort, there was less blood loss (136 vs. 489 mL), a shorter operative time (161 vs. 200 minutes), similar hospital stay (five days), and a similar percentage of complications (22.4 vs. 22.5%). Approach-related complications in the open cohort included wound infection and dural tears.

In 2010, Isaacs et al reported perioperative outcomes from a prospective multicenter (14 sites) observational study of the XLIF procedure for adult patients with degenerative scoliosis. A total of 107 patients (mean age, 68 years, and range 45-87) underwent XLIF either with or without supplemental posterior fusion. A mean of 4.4 levels (range, 1-9) were treated per patient. The addition of supplemental instrumentation (anterior, lateral, or posterior), the use of direct decompression, the addition of a posterior approach, and the inclusion of L5-S1 was left to the choice of the surgeon. Supplemental pedicle screw fixation was used in 75.7% of patients, 5.6% had lateral fixation and 18.7% had stand-alone XLIF. The mean operative time was 58 minutes/level and the mean blood loss was 50 to 100 mL. Nine patients (8.4%) had >300 mL blood loss. The mean hospital stay was 3.8 days (2.9 days for unstaged procedures and 8.1 days for staged procedures). Of the 36 patients (33.6%) with some evidence of weakness after surgery, 86.2% had transient weakness that was thought to be related to passage of retractors through the psoas muscle. Major complications occurred in 12.1% of patients overall. In patients who had XLIF alone or with percutaneous instrumentation, major complications occurred in 9% of patients. In patients with supplemental open posterior instrumentation, 20.7% had one or more major complication. The strongest independent predictor of complications was the total number of levels operated per patient. The authors concluded that the rate of major complications compares favorably to that reported from other studies of surgery for degenerative deformity.

In 2010, Rodgers et al published a retrospective review of a database for all patients treated with the XLIF procedure by a single surgeon (between 2006 and 2008), focusing on early complications (< 3 months) in obese and nonobese patients. Out of a total of 432 patients treated with XLIF during this period, 313 (72%) met the inclusion criteria for the study and had complete data; 156 were obese (> 30 kg/m2) and 157 were not obese. Patients who were obese

were slightly younger (58.9 vs. 62.9 years of age) and had a higher incidence of diabetes mellitus (48 vs. 17) than patients who were not obese, but were otherwise comparable at baseline. There were 27 complications (8.6%) in the entire group, which included cardiac and wound complications, vertebral body fractures (one requiring reoperation), nerve injuries, gastrointestinal injuries (one requiring reoperation), and hardware failures (one requiring reoperation for recurrent stenosis after cage subsidence). The complication and reoperation rates were not significantly different between the obese and nonobese groups. There were no cerebrospinal fluid leaks, no infections, and no patient required transfusion. The average length of hospital stay was 1.2 days. The authors noted that reliable automated neurological monitoring and fluoroscopic guidance, and meticulous attention to operative technique are required, but that the early outcomes compare well with traditional interventions.

In 2011, Rodgers et al reported a retrospective analysis of intraoperative and perioperative complications from all consecutive patients (600 procedures, 741 levels) treated by two surgeons since the XLIF procedure was introduced at their institution. Four-hundred eighty-five procedures were single level, 90 were two levels, and 25 involved three or more levels. The hospital stay averaged 1.2 days. There were 37 complications (6%), classified into medical (60%) and surgical (40%). Surgical complications included four transient postoperative neurologic deficits and one subcutaneous hematoma. There were no wound infections, no vascular injuries, and no intraoperative visceral injuries in this series. At a minimum one-year follow-up, VAS pain scores had decreased from an average 8.8 to 3.1.

The incidence of cage overhang following XLIF or DLIF was reported by Regev et al in 2010. Out of a total of 152 minimally invasive lateral fusion procedures performed at the author's institution between 2005 and 2008, postoperative magnetic resonance imaging or computed tomography scans additional posterior decompression following the anterior procedure or to evaluate patients with recurrent back or radicular pain. Of the 37 cases with post-operative imaging, eight (22%) were found to be hanging outside of the intervertebral space. Six of the interbody cages (15%) had an anterior overhang, which placed them in the vicinity of the retroperitoneal great vessels. The study concluded that the risk of an excessively long interbody cage is high when relying on antero-posterior fluoroscopy for cage insertion in the anterior third of the disc space. The proportion of cases with an excessively long interbody cage out of the total number of procedures cannot be determined from this report.

Searches of the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience database (MAUDE; www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE) identified a number of adverse event reports for NuVasive spinal cage implants, MaXcess XLIF inserter, fiber optic light, and NeuroVision EMG, including instrument malfunction and breakage.

Due to limited evidence and concerns about the safety and efficacy of the lateral transpsoas approach, comparative studies are needed.

Axial Lumbar Interbody Fusion (AxiaLIF) 2012 Update
The literature on axial lumbosacral interbody fusion (axial LIF) consists of case series. No controlled trials have been identified that compare outcomes of axial LIF with other approaches to lumbosacral interbody fusion.

The largest case series published to date is a 2011 retrospective analysis of 156 patients from four clinical sites in the U.S. Patients were selected for inclusion if they underwent a L5-S1 interbody fusion via the axial approach and had both presurgical and two-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 two-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 two years was 94% (145 of 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 two 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 six years. All patients had undergone a minimum of six months (mean, five 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 one 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 to 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.

In 2012, Gerszten et al reported a series of patients who had a minimum two-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. 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 one 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 two years posttreatment, all patients showed solid fusion.

Additional series with fewer than 100 patients are reviewed by Zeilstra et al. Improvement in back pain in these studies ranges from 49% to 67% and improvement in the ODI ranges from 50% to 56%.

In 2010, Patil and colleagues reported a retrospective review of 50 patients treated with axial LIF. 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 three 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, visual analog scale (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 disk space height and lumbar lordosis angle.

Aryan and colleagues reported on a series of 35 patients with average follow-up of 17.5 months in 2008. These patients had pain secondary to lumbar degenerative disc disease, degenerative scoliosis, or lytic spondylolisthesis. In 21 of the patients, the axial LIF procedure was followed by percutaneous pedicle screw-rod fixation; two patients had extreme lateral interbody fusion (XLIF) combined with posterior instrumentation, and 10 had a standalone procedure. Two patients had axial LIF as part of a larger construct after unfavorable anatomy prevented access to the L5-S1 disc space during open lumbar fusion. Radiographic evidence of stable cage placement and fusion was found in 32 patients at last follow-up.

Axial LIF with percutaneous pedicle screw reduction has also been described for Grade 2 spondylolisthesis in a case series of three patients.

Adverse Events

An industry-sponsored five-year voluntary postmarketing surveillance study of 9,152 patients was reported by Gundanna et al in 2011. 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 three months to five years three months. Complications were reported in 120 patients (1.3%) at a median of five 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. 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 months' 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 two 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 prior to 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.

Summary

Current evidence for some minimally invasive/minimal (ALIF, PLIF, TLIF) access approaches includes systematic reviews and non-randomized comparative studies. The available evidence suggests that after an initial training period, short to mid-term health outcomes (including complication and fusion rates, pain and function) following minimally invasive anterior, posterior, and transforaminal approaches are comparable to standard open approaches for single-level interbody fusion of the lumbar spine. Intra and peri-operative health outcomes (blood loss and hospital stay) have been shown to be improved.

There is insufficient evidence to evaluate the efficacy of ALIF, PLIF, and TLIF for interbody fusion of more than one level of the lumbar spine. Therefore, multi-level lumbar interbody fusion using ALIF, PLIF or TLIF is considered investigational. The available evidence suggests the possibility of an increased risk of complications with laparoscopic ALIF.

The available published evidence on axial LIF consists of case series. This evidence is insufficient to evaluate whether axial LIF is as effective or as safe as other surgical approaches to lumbosacral interbody fusion, 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 an increased risk of complications.

Technology Assessments, Guidelines and Position Statements

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) provided guidance on lateral interbody fusion in the lumbar spine in 2009. NICE concluded that current evidence on the safety and efficacy of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

In 2011 the United Kingdom's National Institute for Health and Clinical Excellence (NICE) provided guidance on transaxial inter-body fusion in the lumbar spine. 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.

The American Association of Neurological Surgeons published guidelines for interbody techniques for lumbar fusion in 2005. There was insufficient evidence to recommend a treatment standard. Minimally invasive procedures were not reviewed.

Key Words:

Axial anterior lumbar fusion, AxiaLIF, axial lumbar interbody fusion, anterior lumbar interbody fusion, ALIF, posterior lumbar interbody fusion, PLIF, transforaminal lumbar interbody fusion, TLIF, laparoscopic ALIF, lateral interbody fusion, extreme lateral interbody fusion, XLIF, direct lateral interbody fusion, DLIF, para-axial, pre-sacral interbody fusion, trans-sacral interbody fusion or paracoccygeal interbody fusion, axial LIF, AxiaLIF® system, AxiaLIF II Level system

Approved by Governing Bodies:

The AxiaLIF® (Axial Lumbar Interbody Fusion) and AxiaLIF 2 Level systems were developed by TranS1® and consist of techniques and surgical instruments 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.) U. S. Food and Drug Administration (FDA) premarket notification (510[k]) summaries indicate that the AxiaLIF® (Axial Lumbar Interbody Fusion) and AxiaLIF 2 Level systems procedures are intended 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. The AxiaLIF® systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), 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 2, 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.

Other approaches may also use customized instrumentation, and several tubular retractor systems and pedicle screw-rod instrumentation are cleared for marketing through the FDA 510(k) pathway. These include the MAST QUADRANT™ Retractor System, METRx X-tube and Sextant pedicle screw system, all from Medtronic, and the Viper pedicle screw system from

DePuy. XLIF uses specialized retractors (MaXcess) and NeuroVision EMG nerve monitoring by NuVasive, while DLIF utilizes specialized instrumentation from Medtronic.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification requirements: Not applicable.

Coding:

CPT Codes:	**0195T**	Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace
	0196T	; L4-L5 interspace (List separately in addition to code for primary procedure)
	0309T	Publication of this code is pending the 2013 publication of new Category I codes for companion services relevant to this code. **(Effective 01/01/2013)**
	22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace **(Effective 01/01/2013)**

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Policy History:

Medical Policy Group, April 2011 **(1)**
Medical Policy Administration Committee, May 2011
Available for comment May 25 – July 11, 2011
Medical Policy Panel, November 2011
Medical Policy Group, March 2012 **(2):** Updated Description, Key Points, Key Words, References pertaining to axial lumbosacral interbody fusion
Medical Policy Group, November 2012: 2013 Coding Update – added Code 22586 & 0309T and updated verbiage on 0195T & 0196T
Medical Policy Panel, November 2013
Medical Policy Group, November 2013(**4**)**:** Updated Key Points and References. No changes to the policy statement at the time.
Medical Policy Group, April 2014 **(4):** Updated Approved By Governing Bodies to include name change for Baxano. No changes to the policy statement.