MEDICAL POLICY

Excellus

SUBJECT: MINIMALLY INVASIVE/ MINIMAL ACCESS TECHNIQUES FOR LUMBAR INTERBODY FUSION	EFFECTIVE DATE: 08/20/09 REVISED DATE: 08/19/10, 09/15/11, 10/18/12, 09/19/13, 08/21/14, 08/20/15, 07/21/16, 07/20/17, 6/21/18
POLICY NUMBER: 7.01.83 CATEGORY: Technology Assessment	PAGE: 1 OF: 8

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

I. Based upon our review and assessment of peer-reviewed literature, the following minimally invasive/minimal access techniques for interbody lumbar fusion have been medically proven to be effective and therefore can be considered as a **medically appropriate** treatment alternative to open standard lumbar fusion:
   A. Anterior lumbar interbody fusion (ALIF);
   B. Direct lateral interbody fusion (DLIF);
   C. Extreme lateral interbody fusion (XLIF®);
   D. Posterior lumbar interbody fusion (PLIF); or
   E. Transforaminal lumbar interbody fusion (TLIF).

II. Based upon our criteria and assessment of peer-reviewed literature, the following minimally invasive/minimal access techniques for interbody lumbar fusion have not been medically proven to be effective and are considered **investigational** either as a stand-alone procedure or as an adjunct to standard spinal fusion:
   A. Axial lumbar interbody fusion (AxiaLIF®); or
   B. Laparoscopic anterior lumbar interbody fusion (LALIF).

Refer to Corporate Medical Policy #7.01.90 regarding Lumbar Fusion for Adults.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Lumbar fusion has become a widely accepted method for the management of a variety of disorders that require spinal stabilization, such as traumatic, degenerative, infectious, and neoplastic conditions. Interbody fusion of the lumbar spine can be approached from an anterior, posterior, and lateral direction. These approaches are traditionally performed with an open approach (long incision with wide retraction of the musculature. One of the drawbacks of conventional lumbar fusion is the extensive soft tissue dissection that is necessary in order to expose the anatomic landmarks for screw insertion, achieve a proper lateral-to-medial screw trajectory, and develop an acceptable fusion bed. The tissue injury that occurs during the surgical approach can result in increased postoperative pain, lengthened recovery time, and impaired spinal function. Blood loss during open lumbar fusion surgery can also be quite significant. These conventional approaches can now be performed through minimally invasive/minimal access procedures. A variety of minimally invasive/minimal access procedures are being investigated with the intent of limiting iatrogenic damage to muscular, ligamentous, neural, and vascular structures. Minimally invasive techniques that have been investigated include laparoscopic anterior lumbar fusion (LALIF), 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).

Anterior access provides direct visualization of the disc space through an abdominal incision, 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 Anterior Lumbar Interbody Fusion (LALIF) is a minimally invasive technique that has been proposed as an alternative to the open surgical approach to spinal fusion. This method employs a laparoscope to remove the diseased disc and insert an implant into the disc space intended to stabilize and promote fusion. This technique is evolving as a method of minimizing soft-tissue injury and is associated with a learning curve.

Posterior LIF 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. Minimally invasive/minimal access PLIF uses tubular retractors (e.g., METRx™, Luxor™) to allow access and open visualization of the surgical area. These 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 LIF, performed through an open technique, is also performed through a posterior approach. Access to the spine is through the foramen which is enlarged by removal of surrounding bone. In minimally invasive TLIF, a single incision about 2-3 cm in length is made approximately 3 cm 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.

Axial lumbar interbody fusion (AxiaLIF®, also called anterior para-axial, 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. It is performed percutaneously, under fluoroscopic guidance via the pre-sacral space. Theoretically, this approach avoids the viscera, blood vessels and nerves; preserves normal tissue at the treatment site; provides access to the disc space without interrupting the annulus; and allows for percutaneous longitudinal access to the anterior spine.

Lateral interbody fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF]) 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. The XLIF® surgical technique incorporates two systems developed by NuVasive®: the MaXcess® System and the NeuroVision® JJB System.

Both open and minimally invasive/minimal access 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.

RATIONALE:

Minimal access open anterior, posterior, and transforaminal LIF:

The available evidence (reviews, non-randomized comparative studies) suggests that after an initial training period, the mid-term health outcomes (including complication and fusion rates, pain and function) following minimally invasive anterior, posterior, transforaminal, and extreme lateral (XLIF) 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 (e.g., Kim, et al. 2010; Park, et al. 2007; Ghahreman, et al. 2010; Kasis, et al. 2009; Wang, et al. 2010; Wu, et al. 2010; Shunwu, et al. 2010; Rouben, et al. 2010).

Direct lateral interbody fusion (DLIF):
DLIF procedure utilizes specialized FDA approved instrumentation from Medtronic. While well-designed, comparative clinical trials are needed to demonstrate whether these procedures provide improved health outcomes with long-term follow-up, the outcomes from studies thus far demonstrate that DLIF has comparable outcomes to XLIF. P Berjano et al. (2012) conducted a retrospective cohort review of 97 consecutive patients from three centers with minimum 6-month follow-up (mean 12 months, 93 patients available for follow-up). The main diagnosis was DDD with or without stenosis, or spondylolisthesis, grade I. Functional status was evaluated by preoperative and last follow-up Oswestry Disability Index score. Leg and back pain were evaluated by visual analog scales. Complications were recorded and permanent complications and neurological impairment was actively investigated at last follow-up. Clinical success was considered to be achieved when the patient increased his functional ODI score by more than 12% or decreased his back pain VAS by more than 3 points. No permanent neurological impairment, vascular or visceral injuries were observed by the investigators. Transient neurological symptoms presented in 7% of cases, all resolved within 1 month from surgery. Transient thigh discomfort was observed in 9%. Clinical success was recorded in 92% of cases.

Extreme lateral interbody fusion (XLIF):
While extreme lateral interbody fusion as an endoscopic surgical procedure does not require FDA approval, the instrumentation associated with the XLIF procedure does. NuVasive ® has developed the XLIF® instrumentation/ products for this surgical approach. This minimally invasive surgical platform is known as Maximum Access Surgery (MAS). MAS combines three categories of product offerings- NeuroVision®, MaXcess® and specialized implants such as SpheRx™ and CoRoent™. All surgical instrumentation associated with this procedure has received FDA approval either through the PMA or 510(k) process.

Ozgur et al. (2006) reported on the surgical technique for XLIF of the lower lumbar spine.13 patients with axial low back pain who failed at least six months of conservative management underwent the XLIF technique. The authors concluded that, in comparison to anterior laparoscopic approaches, the XLIF approach had the advantages of not needing to retract the great vessels, not requiring a steep learning curve, and of no impairment to depth perception during the procedure. The most important advantage was a reduction in operative time. In this preliminary report, no complications were associated with the surgery; however, long-term follow-up and efficacy was yet to be reported.

In a 2009 report, Knight and colleagues 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, 6 cases of meralgia paresthetica, and 1 case of significant psoas muscle spasm). In 4 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 mins.), similar hospital stay (5 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, 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 (less than 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 (greater than 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 (1 requiring reoperation), nerve injuries, gastrointestinal injuries (1 requiring reoperation), and hardware failures (1 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 and colleagues reported a retrospective analysis of intraoperative and perioperative complications from all consecutive patients (600 procedures, 741 levels) treated by 2 surgeons since the XLIF procedure was introduced at their institution. Four-hundred eighty-five procedures were single level, 90 were 2 level, and 25 involved 3 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 4 transient postoperative neurologic deficits and 1 subcutaneous hematoma. There were no wound infections, no vascular injuries, and no intraoperative visceral injuries in this series. At a minimum 1-year follow-up, VAS pain scores had decreased from an average 8.8 to 3.1.

Laparoscopic anterior interbody lumbar fusion:
Currently, the published, peer-reviewed scientific literature does not allow strong conclusions regarding the overall benefit and long-term efficacy of the laparoscopic anterior approach compared to open spinal fusion. Studies also report a potentially a higher rate of complications with laparoscopic ALIF.

In review of the literature on laparoscopic ALIF, Inamasu et al, (2005) identified 19 studies which described the outcome of a L5-S1 laparoscopic ALIF, 9 studies which described the outcome of the L4-L5 laparoscopic ALIF, and 8 studies which described the outcome of a 2-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 by Regan, et al, 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 1 or 2 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 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, pulmonary embolism) were significantly lower in the laparoscopy group (0% vs. 2%). Postoperative complications were similar in the 2 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. 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 2 interbody cages placed.

AxiaLIF:

The AxiaLIF and AxiaLIF 2 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 2 level system received premarket notification in April 2008. FDA premarket notification [510(k)] summaries indicate that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of interbody fusion.

There is insufficient evidence to determine if axial lumbar interbody fusion is as effective or as safe as other established surgical techniques.

Aryan and colleagues report on their series of 35 patients with average follow-up of 17.5 months. These patients had pain secondary to lumbar degenerative disc disease, degenerative scoliosis, or lytic spondylolisthesis. In 21 of the patients, the AxiaLIF procedure was followed by percutaneous pedicle screw-rod fixation, 2 patients had extreme lateral interbody fusion combined with posterior instrumentation, and 10 had a stand-alone 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. Thirty-two patients had radiographic evidence of stable cage placement and fusion at last follow-up.

In 2010, Patil and colleagues reported a retrospective review of 50 patients treated with AxiaLIF. Four patients (8%) underwent 2-level AxiaLIF and 16 patients (32%) underwent a combination of AxiaLIF with another procedure for an additional level of fusion. There were 3 reoperations due to pseudoarthrosis (n=2) and rectal injury (n=1). Other complications included superficial infection (n=5), hematoma (n=2), and irritation of a nerve root by a screw (n=1). At 12- to 24-month follow-up VAS scores had decreased from 8.1 to 3.6 (n = 48). At an average 12-month follow-up, 47 of 49 patients (96%) with postoperative radiographs achieved solid fusion. There were no significant differences between pre- and postoperative disk space height and lumbar lordosis angle.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT: Minimally invasive/minimal access ALIF, PLIF or TLIF would be billed using open lumbar fusion/arthrodesis codes.

22586 **(E/I)** Arthrodesis, pre-sacral interbody technique, including disc preparation, discectomy, with posterior instrumentation with image guidance, includes bone graft with preformed, L5-S1 interspace

0195T **(E/I)** Arthrodesis, pre-sacral interbody technique, including disc preparation, discectomy, without instrumentation with image guidance, includes bone graft with preformed, L5-S1 interspace

0196T **(E/I)** L4-L5 interspace (list separately in addition to code for primary

No specific codes exist for billing of DLIF or XLIF

HCPCS: No specific codes

ICD10: Multiple diagnosis codes

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* key article

KEY WORDS:

Axial, Direct Lateral Interbody Fusion, Extracavitary, Extreme lateral, Interbody fusion, Laparoscopic anterior, Minimal access, Paracoccygeal axial approach, Pre-sacral approach, Trans-sacral approach

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, minimally invasive/minimal access lumbar interbody fusion is not specifically addressed in National or Regional Medicare coverage determinations/policies. However, there is currently a Local Coverage Determination (LCD) and related article for Category III CPT codes. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ContrId=298&ver=56&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQAAAAAAA%3d%3d&