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May 1, 2012

Thomas L. Simmer, MD
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Subject: BCBSM Policy on Minimally Invasive Lumbar Interbody Fusion

Dear Dr. Simmer:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and our AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, we would like to thank Blue Cross-Blue Shield of Michigan for the opportunity to comment on the BCBSM medical policy BCBSM Minimally Invasive Lumbar Interbody Fusion. We appreciate the efforts of your team in developing a review of the published literature reporting on the use of minimally invasive procedures for lumbar interbody fusion such as lateral interbody fusion (e.g., extreme lateral lumbar interbody fusion or XLIF, direct lateral lumbar interbody fusion or DLIF), but ***disagree*** that such interventions are considered experimental and investigational, and not medically necessary.

We believe that minimally invasive lateral interbody fusion (e.g., XLIF, DLIF) with direct visualization is a medically necessary option in appropriate patients with medical indications as determined by their treating physician. There is a distinction between percutaneous procedures, in which the surgeon is unable to directly visualize the anatomy being operated on with the naked eye, with minimally invasive (MIS) procedures, which are open procedures using specialized retractors, such as muscle-dilating retractor systems, to allow direct visualization of the spinal structures. Open, or direct visualization, lateral interbody fusion procedures are reported with the appropriate CPT code:

- **CPT 22558** Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar

Lateral lumbar interbody fusion fusions are accomplished by direct visualization of the bony anatomy and the neural elements, whether by exposures with traditional retractors or by muscle dilating minimal access retractors, which may be considered equivalent. In both of these instances, the same anatomy, i.e., vertebral body, disc space, psoas muscle, etc., are directly visualized for the procedure. **This is distinct from percutaneous techniques, where the procedure is performed with fluoroscopy or image guided systems without direct visualization of the anatomy.** The evidence to support minimally invasive techniques as a viable alternative to traditional open procedures continues to accumulate in the literature.

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In the Medical Policy Statement summary, BCBS of Michigan holds the position that "There is insufficient published evidence to evaluate whether... lateral interbody fusion, which may be called extreme lateral interbody fusion (XLIF) or direct lateral interbody fusion (DLIF), (is) as effective or as safe as other surgical techniques." This statement is based on a 2011 literature review, which cited only 6 studies of lateral interbody fusion. To date, more than 40 studies have confirmed the utility and efficacy of the lateral, transpsoas approach to the lumbar spine for interbody arthrodesis. The Medical Policy Statement is based on a very small selection of these studies and lacks the substantial evidence that clearly establishes lateral interbody fusion as an effective, safe option for treatment of numerous lumbar spine conditions. In the evidentiary summary section, the Medical Policy states, "Due to limited evidence and concerns about the safety and efficacy of the lateral transpsoas approach, comparative studies are needed." However, as detailed below, several studies have directly compared outcomes between lateral interbody fusion and either open anterior lumbar interbody fusion (ALIF) or posterior approaches. Unfortunately, these studies were not included in the evidence-based review underlying the Medical Policy.

The AANS and CNS therefore request that the Medical Policy Statement take into consideration the full extent of available medical evidence regarding the lateral, transpsoas approach for interbody fusion. Numerous studies provide clear evidence supporting lateral interbody fusion with respect to clinical effectiveness and an equivalent complication profile to ALIF and TLIF/PLIF, which did not appear to have been included into your current medical policy statement.

Description of Minimally Invasive Lateral Interbody Fusion (e.g., XLIF, DLIF)

The principal goal of the minimally invasive lateral, transpsoas approach for interbody fusion is to gain access to the lumbar spine for treatment of spinal disorders, such as degenerative spondylosis. We concur with the Medical Policy Statement in identifying lateral interbody fusion as a variant of the ALIF. In the lateral transpsoas approach, the patient is securely placed in the lateral position and two small incisions are made. Utilizing intraoperative fluoroscopy to identify the correct spinal level and electrophysiological neuromonitoring for identification of the lumbar plexus and nerve roots, a dilator is then inserted through the lateral incision and then through the psoas muscle to the lateral aspect of the vertebral body or annulus fibrosus. The psoas is sequentially dilated and the table-mounted retractor inserted, always monitoring for electromyographic (EMG) proximity stimulation to the nerves of the lumbar plexus. The retractor is then opened and a shim is introduced via the dorsal retractor blade into the disk space. Once the retractor is opened, this permits direct visualization of spinal anatomy with the naked eye, as with ALIF. Also, as is the case with ALIF, a radical discectomy is then performed, followed by placement of an intervertebral fusion device. This permits both direct and indirect decompression of neural elements and arthrodesis, equivalent to ALIF.

The lateral trans-psoas approach continues to gain increasing use by spine surgeons seeking to perform lumbar interbody fusion in a minimally disruptive fashion in those patients who would benefit as compared to other techniques. Patients who would benefit from the trans-psoas approach are those who require an anterior lumbar interbody fusion, yet need avoidance of mobilization of the great vessels or the hypogastric plexus, such as those with prior abdominal surgery or associated abdominal comorbidities.

Complication Profile of Minimally Invasive Lateral Interbody Fusion (e.g., XLIF, DLIF)

Several reports have published the complication profile associated with the lateral interbody procedure and documented that complication rates overall is equivalent or better than the traditional ALIF procedure. With respect to general surgical complications, the overall complication rate is significantly

lower after lateral interbody fusion (8.2%) compared to anterior lumbar interbody fusion (16.7%) as reported by Smith et al (Smith et al, 2012). Youssef et al. also reported a 2.4% perioperative complication rate in a cohort of 84 patients undergoing lateral interbody fusion, again significantly lower than rates after open ALIF (Youssef, 2010). The reported infection rates are generally low for lateral interbody fusion, ranging from 0.0% - 0.01% (Berjano, 2012; Rodgers, 2010; Knight, 2009). Furthermore, the rates of blood transfusion following lateral interbody fusion are low. Rodgers et al. reported a transfusion rate of 0.2% in their large series. This compares favorably to reported literature for anterior-posterior fusion (4.7%), and instrumented posterolateral fusion (26.5%) (Rodgers, 2011). In a study comparing lumbar fusion with either XLIF or open PLIF in geriatric patients over 80 years of age, Rodgers et al. observed a significantly lower complication rate (7.5% vs. 60%), less blood loss (Hgb change 1.4g vs. 2.7g), lower transfusion rate (0.0% vs. 70%), and shorter length of stay (1.3days vs. 5.3days). The overall mortality was significantly lower in the lateral interbody fusion group (2.5%) than in the open PLIF group (30%) (Rodgers, 2010).

Though there has been an isolated case report of visceral injuries following lateral interbody fusion (Tormenti, 2010), there were no vascular or visceral injuries in a series of 600 patients undergoing lateral interbody fusion (Rodgers, 2011) as compared to the risk of vascular injury for open ALIFs is as high as 1.9-3% (Sasso, 2005; Fantini, 2007; Brau, 2004). Another major risk of the open ALIF approach is retrograde ejaculation, occurring in 0.6-4.5% of men (Sasso, 2003). There have been no reported cases of retrograde ejaculation following lateral interbody fusion. This can be attributed to the fact that the sympathetic plexus is not mobilized during the lateral transpsoas approach and is one of several distinct advantages of the lateral, transpsoas approach. Finally, motor deficits reported after lateral interbody fusion have been reported to range from 0.3%-2.9% (Pumberger, 2011; Rodgers, 2011; Youssef, 2010) with majority of the cases resolving spontaneously within three months. It is comparable to the reported rates in PLIF (1.0-6.1%) (Krishna, 2008; Okuda, 2006; Kim, 2006) and MIS TLIF (4.1%) (Villavicencio, 2006) procedures.

Summary

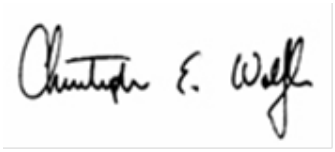
The minimally invasive lateral interbody fusion (e.g., XLIF, DLIF) with direct visualization represents a safe, effective, minimally invasive technique and we would request the BCBS of Michigan Medical Policy be revised to reflect as such. Indeed, the Medical Policy Statement, as written, already agrees that MIS TLIF and MIS PLIF are equally as safe as open TLIF and open PLIF. As documented above, the literature supports minimally invasive lateral interbody fusion (e.g., XLIF, DLIF) with direct visualization as an equivalent technique to ALIF performed with direct visualization. **We believe that minimally invasive lateral interbody fusion (e.g., XLIF, DLIF) with direct visualization is a medically necessary option in appropriate in patients with medical indications as determined by their treating physician.**

We appreciate the opportunity to review and comment on the BCBSM Policy On Minimally Invasive Lumbar Interbody Fusion. We recognize that minimally invasive lateral interbody fusion (e.g., XLIF, DLIF) with direct visualization is a costly technology and is not appropriate for all patients who need an interbody fusion. **However, we believe that for many patients with spinal disorders, minimally invasive lateral interbody fusion with direct visualization may be a beneficial and necessary option for many patients and should not be considered "investigational and not medically necessary".**

Again, thank you for this opportunity to comment and we hope you will reconsider your medical policy. If you have any questions, please feel free to contact us.

Sincerely,

Mitchel S. Berger, MD, President
American Association of Neurological Surgeons



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References

Bergey DL, Villavicencio AT, Goldstein T, et al. Endoscopic lateral transpsoas approach to the lumbar spine. Spine 2004;29:1681–8

Berjano P, Balsano M, Buric J, Petruzzi M, Lamartina C. Direct lateral access lumbar and thoracolumbar fusion: preliminary results. European Spine Journal 21:37-42, 2012

Brau SA, Delamarter RB, Schiffman ML, et al. Vascular injury during anterior lumbar surgery. Spine J 2004;4:409–12.

Fantini GA, Pappou IP, Girardi FP, et al. Major vascular injury during anterior lumbar spinal surgery. Spine 2007;32:2751–8.

Kim KT, Lee SH, Lee YH, et al. Clinical outcomes of 3 fusion methods through the posterior approach in the lumbar spine. Spine 2006;31:1351–7.

Knight RQ, Schwaegler P, Hanscom D, et al. Direct lateral lumbar interbody fusion for degenerative conditions: early complication profile. J Spinal Disord Tech 2009;22:34–7.

Krishna M, Pollock RD, Bhatia C. Incidence, etiology, classification, and management of neuralgia after posterior lumbar inter- body fusion surgery in 226 patients. Spine J 2008;8:374–9.

Laws CJ, Coughlin DG, Lotz JC, Serhan HA, Hu SS. Direct Lateral Approach to Lumbar Fusion is a Biomechanically Equivalent Alternative to the Anterior Approach: An in vitro Study. Spine (Phila Pa 1976) 2011.

Okuda S, Miyauchi A, Oda T, et al. Surgical complications of posterior lumbar interbody fusion with total facetectomy in 251 patients. J Neurosurg Spine 2006;4:304–9.

Park P, Foley KT. Minimally invasive transforaminal lumbar interbody fusion with reduction of spondylolisthesis: technique and outcomes after a minimum of 2 years' follow-up. Neurosurg Focus 2008;25:E16.

Pumberger M, Hughes AP, Huang RR, Sama AA, Cammisa FP, Girardi FP. Neurologic deficit following lateral lumbar interbody fusion. Eur Spine J, 2011.

Rodgers WB, Gerber EJ, Patterson J. Intraoperative and early postoperative complications in extreme lateral interbody fusion: an analysis of 600 cases. Spine (Phila Pa 1976) 2011;36:26-32.

Rodgers WB, Gerber EJ, Rodgers JA. Lumbar fusion in octogenarians: the promise of minimally invasive surgery. Spine (Phila Pa 1976) 2010;35:S355-60.

Sasso RC, Best NM, Mummaneni PV, et al. Analysis of operative complications in a series of 471 anterior lumbar interbody fusion procedures. Spine 2005;30:670–4.

Sasso RC, Kenneth Burkus J, LeHuec JC. Retrograde ejaculation after anterior lumbar interbody fusion: transperitoneal versus retroperitoneal exposure. Spine (Phila Pa 1976). 2003 May 15;28(10):1023-6. PubMed PMID: 12768143.

Smith WD, Christian G, Serrano S, Malone KT. A comparison of perioperative charges and outcome between open and mini-open approaches for anterior lumbar discectomy and fusion. J Clin Neurosci 2012;19:673-80.

Tormenti MJ, Maserati MB, Bonfield CM, Okonkwo DO, Kanter AS. Complications and radiographic correction in adult scoliosis following combined transpsoas extreme lateral interbody fusion and posterior pedicle screw instrumentation. Neurosurg Focus. 2010 Mar;28(3):E7. PubMed PMID: 20192667.

Villavicencio AT, Burneikiene S, Bulsara KR, et al. Perioperative complications in transforaminal lumber interbody fusion versus anterior-posterior reconstruction for lumbar disc degenerations and instability. J Spinal Disord Tech 2006;19:92–7.

Youssef JA, McAfee PC, Patty CA, Raley E, DeBauche S, Shucosky E, et al. Minimally invasive surgery: lateral approach interbody fusion: results and review. Spine (Phila Pa 1976) 35:S302-311, 2010