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DATE OF REVIEW: OCTOBER 15, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Lumbar fusion L4-5, L5-S1 (360 degree)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This case was reviewed by a Texas licensed MD, specializing in Orthopedic Surgery.

REVIEW OUTCOME:

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
Lumbar fusion L4-5, L5-S1, (360 degree)	unavailable	Upon approval	Upheld adverse determination

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Description of records	Date:
Lumbar MRI –Center	03/09/06
Lumbar Discogram & X-Rays of chest and lumbar spine –Center	09/22/06
Post discogram CT Scan of full lumbar spine –Center	09/22/06
Intradiscal marcaine and Steriod injection at L4-L5 & L5-S1 –Center	09/22/06
Utilization review determination – Adverse determination for decompression & fusion L4-SI - ODG guidelines with criteria included –	11/06/06
Initial Orthopaedic Consultation –MD	03/08/07
Utilization review appeal determination – Adverse determination for L4/5 L5/S1 360 degree fusion – ODG guidelines and criteria included	03/28/07
Office Visit –MD	08/13/07
X-rays of lumbar spine – 3 views –Center	08/17/07
Utilization review determination – Adverse determination for lumbar fusion L4-L5-SI 360 degree – ODG guidelines with criteria included –	08/24/07
Utilization review appeal request –Inst.	09/06/07
Utilization review appeal determination – Adverse determination for lumbar fusion L4, L5-SI 360 degree – ODG guidelines with criteria included –	09/13/07
Request for IRO –MD	09/25/07

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who fell off a roof which was one story high. The date of injury. The request is for a 360 degree fusion from L4 to S1. The requestor is Dr. There was an MRI done. It showed disc desiccation

from L4-S1 with only bulges. A discogram done September 2006 resulted in concordant pain at L4-5 and L5-S1. The CT scan revealed annular fissuring and radial tears with extravasation of dye into the epidural space at L4-5. He patient has had physical therapy and epidural steroid injections. An EMG reportedly showed left L5 radiculopathy. The patient is taking Zoloft, Lyrica, and Soma.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The patient is a male with low back pain of approximately years duration. On March, 2007 the lumbar range of motion per Dr. exam was essentially within normal limits. There was no documentation of radiculopathy, nerve root compression or instability, only degenerative disc disease.

It appears that the 360 degree fusion from L4 to S1 is based mainly upon subjective complaints of pain and a reportedly positive discogram at L4-5 and L5-S1. However, discography is not recommended and remains a controversial diagnostic tool (ODG, 4th ed, p 809, 2006). It does not identify the different types of internal disc disease and is further highly influenced by psychological factors. Patients with chronic pain and/or an abnormal psychological profile typically have false positive discograms (ACOEM, Chap 12, p 303, 2004). Therefore, pre-discogram psychological testing is strongly recommended (this patient did not have one). Also, studies have shown that patients with concordant pain have much lower pain tolerance when compared to controls with non-responsive discography (Spine Vol 5, Number 4, July/August 2005). Also a measurement of the quality and quantity of pain response has been a problem. Between no pain and little pain response and concordant severe pain response during discography, there is a wide gray zone in which interpretation of pain responses is very difficult, if not impossible. This is further complicated by the degree of sedation during the procedure, the technical skill of the operator and most importantly, the psychological profile of the patient (Orthopedic Knowledge Update, No 2, p334). The Agency for Healthcare Policy and Research states that there is limited evidence that **discography** can help select patients who would benefit from spinal fusion. What is clear from 40+ frustrating years of **discography** research is that not everyone who reports pain when a disc is injected has the same clinical problems. The best indicator that these patients do not have the same disc problem is that each successive approach to the treatment of patients with "positive discograms" has failed to give consistent good results (Carragee, Stanford University Spine, Volume 24, Number 4, page 372, 1999). Consequently, **discography** should not be used as a stand alone procedure upon which surgery is performed. This information should be correlated with the patient's history, objective physical findings, results of other diagnostic evaluations and psychological evaluation. A positive **discogram** is just one test and it does not equate with surgery (North American Spine Society, Contemporary Spine Care, "Lumbar Discography", pgs 1-21, 2001).

Lumbar spine fusion is not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "Patient Selection Criteria for Lumbar Spinal Fusion," after 6 months of conservative care.

After screening for psychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease with spinal segment collapse with or without neurologic compromise after 6 months of recommended conservative therapy . For complete references, see separate document with all studies focusing on Fusion (spinal). There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo, or conservative treatment. Studies conducted in order to compare different surgical techniques have shown success for fusion in carefully selected patients. (Gibson-*Cochrane*, 2000) (Savolainen, 1998) (Wetzel, 2001) (Molinari, 2001) (Bigos, 1999) (Washington, 1995) (DeBarard-*Spine*, 2001) (Fritzell-*Spine*, 2001) (Fritzell-*Spine*, 2002) (Deyo-*NEJM*, 2004) (Gibson-*Cochrane/Spine*, 2005) (Soegaard, 2005) (Glassman, 2006) (Atlas, 2006) According to the recently released AANS/NASS Guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the 2-year follow up it appeared that pain had significanty increased in the surgical group from year 1 to 2. Follow-up post study is still pending publication. In addition, there remains no direction regarding how to define the "carefully selected patient." (Resnick, 2005) (Fritzell, 2004) A recently published well respected international guideline, the "European Guidelines," concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 years of all other recommended conservative treatments – including multidisciplinary approaches with combined programs of cognitive intervention and exercises – have failed, or such combined programs are not available, and only then in carefully selected patients with maximum 2-level degenerative disc disease. (Airaksinen, 2006) For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. (Ivar Brox-*Spine*, 2003) (Keller-*Spine*, 2004) (

Fairbank-*BMJ*, 2005) (Brox, 2006) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. (Bagnall-*Cochrane*, 2004) (Siebenga, 2006) A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times as high as denial rates using non-guideline based UR. (Wickizer, 2004) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. (Weiner-*Spine*, 2004) (Shah-*Spine*, 2005) (Abelson, 2006) Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. (Deyo-*Spine*, 2005) (Weinstein, 2006) Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (van Tulder, 2006) (Maghout-Juratli, 2006) Despite the new technologies, reoperation rates after lumbar fusion have become higher. (Martin, 2007) According to the recent Medicare Coverage Advisory Committee Technology Assessment, the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment for elderly patients. (CMS, 2006) When lumbar fusion surgery is performed, either with lateral fusion alone or with interbody fusion, unlike cervical fusion, there is no absolute contraindication to patients returning even to contact sports after complete recovery from surgery. Like patients with a thoracic injury, those with a lumbar injury should be pain free, have no disabling neurological deficit, and exhibit evidence of bone fusion on x-ray films before returning. (Burnett, 2006) A recent randomized controlled trial comparing decompression with decompression and instrumented fusion in patients with foraminal stenosis and single-level degenerative disease found that patients universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. (Hallett, 2007) Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurological deficits.
lumbar fusion in workers' comp patients : In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, and this treatment for this condition remains "under study." It appears that workers' compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. (Fritzell-*Spine*, 2001) (Harris-*JAMA*, 2005) (Maghout-Juratli, 2006) (Atlas, 2006) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. (Texas, 2001) (NCCI, 2006) Presurgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers' compensation status, smoking, depression, and litigation were the most consistent presurgical predictors of poorer patient outcomes. Other predictors of poor results were number of prior low back operations, low household income, and older age. (DeBerard-*Spine*, 2001) (DeBerard, 2003) (Deyo, 2005) (LaCaille, 2005) (Trief-*Spine*, 2006) Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. (LaCaille, 2007)

Therefore, based upon the above rationale, the request is not certified.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

ODG:

ODG, Treatment, Fusion (spinal)

TEXAS DEPARTMENT OF INSURANCE COMPLAINT PROCESS: the Texas Department of Insurance requires Independent Review Organizations to be licensed to perform Independent Review in Texas. To contact the Texas Department of Insurance regarding any complaint, you may call or write the Texas Department of Insurance. The telephone number is 1-800-578-4677 or in writing at: Texas Department of Insurance, PO Box 149104 Austin TX, 78714. In accordance with Rule 102.4(h), a copy of this Independent Review Organization (IRO) Decision was sent to the carrier, the requestor and claimant via facsimile or U.S. Postal Service from the office of the IRO on 10/15/07.