

Notice of Independent Review Decision

DATE OF REVIEW:

09/22/2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Inpatient lumbar surgery revision lumbar surgery, hardware removal, laminectomy, discectomy, arthrodesis with cages, posterior instrumentation, and implantation of a bone growth stimulator (EBI) at L3-4 with two day inpatient stay.

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

Board Certified Orthopaedic Surgeon

REVIEW OUTCOME

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

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

Inpatient lumbar surgery; revision lumbar surgery, hardware removal, laminectomy, discectomy, arthrodesis with cages, posterior instrumentation, implantation of a bone growth stimulator (EBI) at L3-4 with two day inpatient stay is not medically necessary.

PATIENT CLINICAL HISTORY (SUMMARY):

The injured individual is a male who was reported to have sustained a work- related injury on xx/xx/xx. The described mechanism of injury was lifting buckets full of mud while pouring a concrete foundation. There is no information regarding initial care or treatment until an operative note dictated by M.D. on 08/10/2007. The injured individual underwent a L4-S1 discectomies, fusion and placement of a bone stimulator. There is no information regarding how the injured individual did following the index procedure. The next note is an operative report for a revision surgery performed on 03/06/2008 by Dr.. This included revision surgery at L4-L5 bilaterally and removal of the bone stimulator. There is no information about how the injured individual responded to the revision procedure until a note dated 05/13/2008. Dr. reported that the injured individual had groin and scrotal pain. His diagnosis on 06/03/2008 was adjacent segment disease with acute herniation of nucleus pulposus (HNP). A lumbar spine MRI with contrast was performed on 06/27/2008. It revealed a mild annular bulge with mild bilateral recess narrowing according to M.D. The injured individual underwent bilateral L3 transforaminal steroid injection with trigger point injections on 07/10/2008 performed by M.D. Dr. then recommended the proposed surgical procedure on the visit of 07/29/2008. He felt that flexion/extension views showed instability. There is no formal documented report consistent with instability in the record reviewed.

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

The injured individual is a male. He has undergone two lumbar procedures with continuing symptoms in the last year. There is no information regarding the clinical response following either the index or revision procedure. He presented again in May 2008 with groin/scrotal pain. The pain generator has not been clearly defined based upon the available medical record or diagnostic studies.

The evidence-based Official Disability Guidelines:

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should include all of the following: (1) All pain generators are identified and treated; & (2) All physical medicine and manual therapy interventions are completed; & (3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI demonstrating disc pathology; & (4) Spine pathology limited to two levels; & (5) Psychosocial screen with confounding issues addressed. (6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. (Colorado, 2001) (BlueCross BlueShield, 2002).

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](#)) A recent study of 725 workers' comp patients in Ohio who had lumbar fusion found only 6% were able to go back to work a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. ([Nguyen, 2007](#))

Fusion (spinal): 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. For workers' comp populations, see also the heading, "Lumbar fusion in workers' comp patients." 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 compliance with recommended conservative therapy. [For spinal instability criteria, see AMA Guides (Andersson, 2000)] 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 significantly 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) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic

diagnoses may predict outcomes from treatment, surgical or otherwise. (Derby, 2005) (Derby2, 2005) (Derby, 1999) New research shows that healthcare expenditures for back and neck problems have increased substantially over time, but with little improvement in healthcare outcomes such as functional disability and work limitations. Rates of imaging, injections, opiate use, and spinal surgery have increased substantially over the past decade, but it is unclear what impact, if any, this has had on health outcomes. (Martin, 2008) The efficacy of surgery for nonspecific back pain is uncertain. There may be some patients for whom surgery, fusion specifically, might be helpful, but it is important for doctors to discuss the fact that surgery doesn't tend to lead to huge improvements on average, about a 10- to 20-point improvement in function on a 100-point scale, and a significant proportion of patients still need to take pain medication and don't return to full function. (Chou, 2008) 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.

Adjacent segment disease/degeneration (fusion): Recommend consider risk factors below. The term "adjacent segment disease" had been defined as the development of new clinical symptoms that correspond to radiographic changes adjacent to the level of a previous spinal fusion. Development appears to be most common above posterior lumbar fusions and at the levels of the thoracolumbar junction and the lumbosacral junction. It is unclear as to whether the radiographic and clinical findings are the result of the spinal fusion, a progression of naturally occurring degenerative disease, or both of these factors. Surgical treatment has shown limited success in providing pain relief or increased function. The term "adjacent segment degeneration" is used to describe radiographic changes seen at levels adjacent to the fused segment that do not necessarily correlate with clinical findings. There is a lack of clear incidence after fusion, and it is unclear whether the artificial disc will decrease the risk. (Hilibrand, 2004) (Park, 2004) A 20-year MRI and functional outcome follow-up study was performed on patients who had undergone fusion to evaluate whether or not degeneration is related to adjacent level fusion, and it concluded that the majority of degenerative changes seen occurred over multiple levels or at levels not adjacent to the fusion, suggesting that changes seen may be more likely related to constitutional factors as opposed to the increased stresses arising from the original fusion. (Wai, 2006) A recent cohort study concluded that instrumented posterolateral lumbar fusion can be a cause of sacroiliac joint (SIJ) degeneration. Adjacent segment degeneration following spinal fusion has attracted considerable attention, but little attention has been paid to the SIJ, which is one of the adjacent joints. In this study the incidence of SIJ degeneration in the fusion group was 75%, which was significantly higher than that of the control group, 38%. (Ha, 2008) See Fusion (spinal).

Risk Factors: (1) Instrumentation, which shortens the interval to occurrence; (2) Posterior lumbar interbody fusion procedures; (3) Placement of a superior pedicle screw, due to damage of the inferior facet of the adjacent segment; (4) Sagittal alignment; (5) Pre-existent degenerative disc at the adjacent segment to the fusion; (6) Spinal stenosis as the indication for the original surgery; (7) Age, thought to be secondary to decreased ability of the spine to accommodate the biomechanical alterations; (8) Osteoporosis; (9) Female gender; (10) Fusion length; & (11) Smoking (Battie, 2002).

The information reviewed does not meet the criteria as outlined by the Official Disability Guidelines (ODG). The patient's current status and its relationship to the original work injury is unclear at best. There are no recent diagnostic studies that clearly support the requested third surgical procedure. Both the evidence-based Medical Disability Advisor and ODG recommend investigation and addressing of nonphysical factors (psychosocial, workplace, or socioeconomic) in cases of delayed recovery or return to work. There is no information regarding any psychosocial testing.



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88 Black Falcon Avenue, Suite 353 Boston, MA 02210 (T) 800-227-1464 (F) 617-375-7777

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES