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DATE OF REVIEW: October 24, 2008

IRO CASE #:

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

This case was reviewed by an Orthopaedic Surgeon, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

360 fusion L4-5 with revision L4-5 laminectomy and discectomy and four-day inpatient stay

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: Overturned (Disagree)

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records, the patient is a male who sustained an industrial injury on xx/xx/xx involving the lumbar spine. The records include an April 17, 2008 utilization review report which renders a non-certification for the request of 360 lumbar fusion at L4-5 with revision and laminectomy/discectomy. The report states that the patient continues to have low back pain with burning, numbness, and paresthesias down the bilateral lower extremities, right more than left. The symptoms radiate into the dorsum of the foot. The patient underwent an L5-S1 laminectomy and discectomy in April 2000. He was reportedly moving concrete blocks on the date of injury and felt a sudden pain in his low back. A non-certification was apparently rendered.

A letter was submitted by a spine surgeon on May 2, 2008 regarding the denial. The physician noted that the patient has had two previous back surgeries with recurrent disc herniation. In order to try to avoid the fourth and fifth surgery, the physician felt that fusion was indicated. He wanted to do a 360 fusion in order to restore the patient's height, lordosis, and prevent any further recurrent disc herniation at that level. The patient was noted to have weakness and a recurrent disc herniation that is 8 mm in size.

The case was again reviewed on May 14, 2008 and another non-certification was provided. The reviewer stated that the patient complains of severe low back pain, radiating to the bilateral lower extremities. He has significantly decreased range of motion with forward flexion. X-rays were reviewed. The patient does appear to have a laminotomy defect at L4-5 and L5-S1. The Official Disability Guidelines were quoted in the report to report states that the patient is status post lumbar laminectomy and discectomy at L4-5 and L5-S1 in the distant past. A May 18, 2007 MRI reportedly showed a large right paracentral disc herniation at L4-5 with disc space narrowing at L5-S1 and neural foraminal narrowing. X-rays from February 27, 2008 showed a degenerative disc. The patient underwent a physical therapy evaluation in October 2007. He saw a spine surgeon on March 28, 2008. He noted a past medical history of a surgical intervention with some complications, including decreased sensation to the right lower extremity and weakness to the right lower extremity. Treatment has included Ambien and Ultram. On physical examination, there was noted decreased range of motion, and some weakness of the right lower extremity muscles including dorsiflexors, plantar flexors, quads, hamstrings, and extensor hallucis longus. Straight leg raise was positive bilaterally, right worse than left with some tenderness of the sacroiliac joint. X-rays were reviewed and showed a laminotomy defect likely at L4-5 and L5-S1. He saw another orthopedic spine surgeon on May 2, 2008 who noted complaints of pain, decreased range-of-motion,

hypoactive reflexes, weakness of the extensor hallucis longus, and weakness of the tibialis anterior. The physician documented that the EMG showed questionable radicular irritation at L5 and L3-4 and he felt that the claimant was a candidate for fusion. This report non-certified the request as there was no documentation or evidence of motion segment instability and no evidence of true progressive neurologic deficit associated with a new injury of xx/xx/xx. It appeared to the physician reviewer that the claimant had residual weakness and sensory complications from the prior surgery as noted by a physician on March 28, 2008. There was no documentation of the results of the psychosocial evaluation to see if the patient would be a good candidate for surgical intervention. There was no documentation that formal physical therapy had been exhausted. There was no documentation that the patient failed conservative measures with injection therapy including facet blocks and epidural injections. It was not clear if the claimant was a smoker or if smoking cessation has been discussed with the treating physicians.

The case was again reviewed on August 19, 2008. A denial was issued. This report documents that the patient treated conservatively with a very brief course of therapy and two epidural steroid injections without long-term relief. The reviewer noted that there is no mention of instability at the level requested and the second opinion spine surgeon on July 29, 2008 suggested that the fusion without instability has a very difficult prognosis. That surgeon suggested a simple discectomy rather than a fusion. It was also noted that the records still do not indicate that a psychological evaluation has been performed.

The records include a May 18, 2007 lumbar MRI report. Findings include L4-5 large right paracentral disc herniation measuring 8 mm posterior to the vertebral body margin. There is mild disc space narrowing. Decreased signal intensity from the disc on T2 weighted images is consistent with decreased water content. At L5-S1, moderate disc space narrowing was noted. There is a broad-based posterior annular disc bulge. This narrows the inferior aspect of both neural foramina.

February 27, 2008 x-rays demonstrated transitional anatomy; degenerative disc disease manifested by disc height loss in the lower lumbar spine; and no evidence for dynamic subluxation with flexion and extension views and no evidence for a pars break.

In reviewing the medical records, an initial complex consultation dated February 27, 2008 notes that the dates of the previous surgeries were 1999 and 2001. The social history states that the patient does not smoke. The report notes that the patient was seen by a neurosurgeon who did recommend surgery, but recommended additional physical therapy. The current physician opined that additional physical therapy will not make a meaningful difference to his presentation. The patient expressed a strong desire to have surgery.

April 25, 2008 electrodiagnostic studies demonstrated the following impression: There is evidence of mild right tibial motor mononeuropathy of uncertain etiology. Clinical correlation was recommended. There were also findings suggestive of mild right femoral motor mononeuropathy of uncertain etiology. The remainder of the study was unremarkable.

The records include a June 13, 2008 pre-authorization request for a psychological evaluation. However, the records fail to document a copy of the psychological evaluation report, if such an evaluation took place.

The patient was seen on July 29, 2008 by an orthopedic surgeon. The report states that other treatment has included physical therapy, but he states that he only had one day of therapy. He had two injections which did not provide him long-term relief. The patient did admit to depression. X-rays from July 29, 2008 showed a transitional L5 segment. There was decreased disc height at L4-5 and retrolisthesis of L3 on L4. The physician stated that he is not able to explain the report of total numbness in the right leg. The surgeon opined that the patient is a potential candidate for further surgery. However, the aspect of the two level fusion without spondylolisthesis of significant instability has a very difficult prognosis as far as getting approval in workers' compensation per the ODG criteria. He may be a candidate for just the aspect of repeat discectomy. The surgeon agreed that he can consider the aspect of the fusion operation at L3-4 and L4-5, but at the same time doing a heavy labor type of work, he is likely to have a breakdown of an adjacent level.

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

The patient demonstrates a large disc herniation at the L4-5 level which protrudes posterior to the vertebral body margin. The Official Disability Guidelines state that until further research has conducted, there remains insufficient evidence to recommend

fusion for chronic low back pain in the absence of stenosis and spondylolisthesis for workers' compensation patients. The patient has both central canal stenosis due to the posterior disc herniation and evidence of neural foraminal stenosis on MRI. The patient demonstrates a retrolisthesis of L3 on L4 per the x-rays of July 2008. He has been through a course of conservative care and one of his physicians has stated that further physical therapy is unlikely to be of benefit. The patient has been referred for a psychological evaluation. It is now clear that the patient is not a smoker. Given this information, the patient meets the criteria specified by the Official Disability Guidelines for proceeding with lumbar fusion. The four-day inpatient stay following surgery is appropriate. Therefore, my recommendation is to overturn the previous decisions to non-certify the request for 360 fusion L4-5 with revision L4-5 laminectomy and discectomy and four-day inpatient stay.

The IRO's decision is consistent with the following guidelines:

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

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME

Official Disability Guidelines (2008): Low Back Chapter:

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) (W etzel, 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. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

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)

Lumbar fusion for spondylolisthesis: Recommended as an option for spondylolisthesis. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis are candidates for fusion. (Eckman, 2005) This study found only a 27% success from spinal fusion in patients with low back pain and a positive single-level low-pressure provocative discogram, versus a 72% success in patients having a well-accepted single-level lumbar pathology of unstable spondylolisthesis. (Carragee, 2006) Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. (Fernandez-Fairen, 2007) Patients with degenerative spondylolisthesis and spinal stenosis who undergo standard decompressive laminectomy (with or without fusion) showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically, according to the recent results from the Spine Patient Outcomes Research Trial (SPORT). (Weinstein-spondylolisthesis, 2007) (Deyo-NEJM, 2007) For degenerative lumbar spondylolisthesis, spinal fusion may lead to a better clinical outcome than decompression alone. No conclusion about the clinical benefit of instrumenting a spinal fusion can be made, but there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion. (Martin, 2007) A recent systematic review of randomized trials comparing lumbar fusion surgery to nonsurgical treatment of chronic back pain associated with lumbar disc degeneration, concluded that surgery may be more efficacious than unstructured nonsurgical care but may not be more efficacious than structured cognitive-behavior therapy. Methodological limitations of the randomized trials prevented firm conclusions. (Mirza, 2007)

Lumbar fusion for Scheuermann's kyphosis: Recommended as an option for adult patients with severe deformities (e.g. more than 70 degrees for thoracic kyphosis), neurological symptoms exist, and pain cannot be adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann's kyphosis. (Lonner, 2007)

Patient Selection Criteria for Lumbar Spinal Fusion:

For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include: (1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital neural arch hypoplasia. (2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical disectomy. [For excessive motion criteria, see AMA Guides, 5th Edition, page 384 (relative angular motion greater than 20 degrees). (Andersson, 2000) (Luers, 2007)] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. 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. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. [For spinal instability criteria, see AMA Guides, 5th Edition, page 379 (lumbar inter-segmental movement of more than 4.5 mm). (Andersson, 2000)] (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability. (6) After failure of two disectomies on the same disc, fusion may be an option at the time of the third disectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Disectomy.)

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)