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Notice of Independent Review Decision

DATE OF REVIEW: February 19, 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 orthopedic 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

Anterior interbody fusion L4-5, additional level L5-S1, retroperitoneal exposure and discectomy L4-5, additional level L5-S1, anterior interbody fixation L4-5, additional level L5-S1, posterior decompression L4-5, additional level L5-S1 transverse process fusion L4-5, additional level L5-S1 posterior internal fixation L4-S1, bone graft allograft in situ, iliac crest, bone marrow aspirate, length of stay 2-3 days

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o September 14, 2007 to January 30, 2008 utilization review reports/letters
- o October 2, 2007 and thorough November 8, 2007 psychological records
- o February 2, 2007 thorough September 28, 2007 paycheck stubs
- o June 26, 2007 rib x-ray report by M.D.
- o August 9, 2007 lumbar spine MRI by M.D.
- o September 13, 2007 CT of lumbar spine with contrast post myelogram report by M.D.
- o December 21, 2007 lumbar discogram report by M.D.
- o July 11, 2007 through December 17, 2007 initial report and progress reports
- o October 26, 2007 electrodiagnostic report
- o September 13, 2007 Designated Doctor report by M.D.
- o September 24, 2007 through January 11, 2008 chart notes by M.D.
- o July 23, 2007 lumbosacral x-ray report by M.D.
- o July 23, 2007 thoracic spine x-ray report by M.D.
- o September 25, 2004 records from Medical Center
- o June 21, 2007 records from Medical Center
- o September 10, 2007 report by M.D.
- o August 15, 2007 bona fide offer of employment
- o July 5, 2007 letters from Insurance
- o June 27, 2007 through August 27, 2007 chart notes from Family Medicine

PATIENT CLINICAL HISTORY (SUMMARY):

According to the medical records, the patient sustained an industrial injury involving the lumbar spine. A non-certification for the above-captioned request was rendered on January 16, 2008. The utilization review report states that the patient was injured in what seems to be a rollover motor vehicle collision. Prior to this in 1989, he had undergone a posterior lateral fusion at the L5-S1 level. This had alleviated his pain allegedly until the motor vehicle accident. The report notes that a psychological interview of November 2007 noted major depression and suggested psychiatric treatment with medications. An August 2007 MRI demonstrated three-level degenerative disc disease according to the utilization review report. A discogram demonstrated three-level degenerative changes with concordant pain at the lower two levels. Electrodiagnostic studies were reportedly normal. The report also notes that the patient is a one pack per day smoker. The non-certification was rendered as the peer review physician stated that the patient was a poor operative candidate because of three level disease, psychological issues, and being a high risk fusion candidate because of nicotine exposure.

The case was again reviewed on January 23, 2008 and another denial was provided. This report notes that the patient is a male who was injured secondary to a motor vehicle accident. The report outlines the imaging findings and electrodiagnostic results. The report outlines the results of a September 24, 2007 physical examination. The examination findings included equal and reactive deep tendon reflexes at the knees and ankles, positive straight leg raise on the right with reproduction of symptoms from the low back to all five toes, muscle strength 5/5 in the extensor hallucis longus and 4/5 in the right dorsi flexor/everters. There was no sensory deficit noted. The conclusion of the report stated that there is evidence of pseudoarthrosis at the level of the previous L5-S1 fusion performed in 1989. The patient underwent psychological evaluation in November 2007 and despite findings of significant major depressive disorder, the patient was cleared for discography. As noted by the previous reviewer, this report states that the patient has three level degenerative disc disease and a history significant for one pack per day smoking. Given the clinical data, the proposed surgical procedure was not recommended as medically necessary.

Lumbar spine x-rays were performed on July 23, 2007 and were found to be normal with no significant degenerative changes. A lumbar spine MRI was performed on August 9, 2007 with an impression as follows: A 3 mm broad-based posterior bulging of the annulus at L4-5 with an associated annular tear. There is resultant mild bilateral foraminal narrowing without significant stenosis centrally. Disc desiccation at L5-S1 with mild to moderate broad-based posterior bulging of the annulus but no significant stenosis. The patient is status post posterior fusion at this level. There is minimal anterior wedge deformity along the T12 vertebral body, likely late subacute to chronic. Minimal edema like signal along the anteroinferior aspect of the T12 vertebral body may be degenerative in nature.

A CT myelogram was performed on September 13, 2007 with an impression as follows: Previous bilateral posterolateral fusion at the L5-S1 level with an osseous fusion mass extending from L5 to S1 adjacent to the posterior elements. This fusion mass is completely incorporated with the posterior elements of S1. However, the fusion mass appears to be only partially incorporated with the posterior elements at the L5 level. There is no central canal or foraminal stenosis at this level. At the L4-5 level, there is a 3 mm generalized disc bulge causing mild effacement of the ventral thecal sac. There is no evidence of a focal disc herniation or nerve root compression at this level. There is also no significant central canal or foraminal stenosis. Partially healed right-sided transverse process fractures present at the L3 and L4 levels. There is no lumbar compression fracture or spondylolisthesis. There is no evidence of significant central canal or foraminal stenosis at any lumbar level. There is also no evidence of a focal lumbar disc herniation or nerve root compression.

A lumbar discogram was performed on December 21, 2007. The impression was no fissure identified at L3-4 and non-concordant pain. At L4-5, a posterior annular fissure was demonstrated and the patient reports concordant pain. At the L5-S1 level, an initial partial annular injection was obtained along the right posterolateral aspect of the disc with subsequent repositioning of the needle. The patient reported concordant pain during this injection. The report notes that it is potentially conceivable that the annular injection may have precipitated some of the pain.

A lumbar post-discogram CT scan was performed with an impression as follows: L3-4 fractures identified in the transverse processes. The fracture through the right L3 transverse process has not healed. There appears to be some partial healing of the fracture through the right L4 transverse process. Contrast material was seen at the nuclear cavity. There is no annular fissure at this level. At L4-5, a broad-based bulge/protrusion is present, which appears to migrate inferiorly slightly behind the body of L5. Contrast material is seen in the nuclear cavity. Contrast material also extends up to the annular periphery posteriorly along its right posterolateral and right lateral aspect. This constitutes a posterior/right posterolateral/right lateral grade 4 fissure. No extra-annular leakage was noted. At L5-S1, a small amount of injected annular contrast material is present along the right posterolateral portion of the disc. This could potentially obscure an annular fissure. It may be of value to repeat the injection at this level to clarify the situation according to the report. There appears to be some posterior annular contrast related to an annular fissure which could be confirmed on repeat injection.

An electrodiagnostic study was completed on October 26, 2007 with an impression of abnormal due to prolonged left tibial F-wave latency. According to the report, this was suggestive of a possible L5 or S1 radiculopathy on the left. There was no evidence of radiculopathy upon EMG test.

On September 13, 2007, the patient underwent a designated doctor evaluation. The patient was noted to have taken medications, however, denied any physical therapy for the injury. He recently switched treating doctors to a chiropractor who planned to start the injured worker on physical therapy. Examination findings included bilateral seated straight leg raise to 90 degrees with no change in pain, bilateral supine straight leg raise to 45 degrees with low back pain and pulling in the ipsilateral

popliteal space, symmetrical sensation to light touch and the lower extremities, right hip flexion/knee flexion/extension all 4+/5, right ankle and toes 1-5 dorsiflexors and plantar flexors are 5/5, left hip flexion and knee flexion-extension 4/5, left ankle and toes 1-5 dorsiflexors and plantar flexors are 4+/5 (all with low back pain), and symmetric lower extremity deep tendon reflexes. The patient was not found to be at maximum medical improvement. Further conservative management was recommended.

Medical records from November 2007 the patient had a caudal epidural steroid injection on October 18, 2007. His pain level reportedly dropped 10 to 15% immediately following the injection, but returned to baseline later that day. This report also states that the patient had undergone one week of active and passive therapy with a chiropractor with no benefit for any period of time. The records do contain multiple pages of chart notes denoting physical therapy since that time.

The patient underwent pre-surgical psychological testing on November 30, 2007. The report notes that the patient has a diagnosis of major depressive disorder, single episode, mild-moderate. It was recommended that he be evaluated for psychopharmacologic treatment, especially appropriateness for the use of antidepressant therapy. However, from a psychological perspective, he was cleared for discography and was deemed a good candidate for spinal surgery if diagnostic results support surgical intervention.

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

According to the Official Disability Guidelines, 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)

The patient is noted to have a significant psychological diagnosis. Although the patient was cleared psychologically for discogram and surgery if necessary, the report also recommended that he be evaluated for psychopharmacologic treatment, especially appropriateness for the use of antidepressant therapy. It would be reasonable for the patient to first undergo this evaluation prior to further consideration for surgery.

In addition, the medical records fail to document that the patient has been able to quit smoking. Given these factors, he does not meet the criteria specified by the Official Disability Guidelines for spinal fusion. Therefore, my recommendation is to uphold the previous determination to non-certify the request for Anterior interbody fusion L4-5, additional level L5-S1, retroperitoneal exposure and discectomy L4-5, additional level L5-S1, anterior interbody fixation L4-5, additional level L5-S1, posterior decompression L4-5, additional level L5-S1 transverse process fusion L4-5, additional level L5-S1 posterior internal fixation L4-S1, bone graft allograft in situ, iliac crest, bone marrow aspirate, length of stay 2-3 days.

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

X 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):
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) 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) 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)

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 - Spondylytic 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 discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

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)