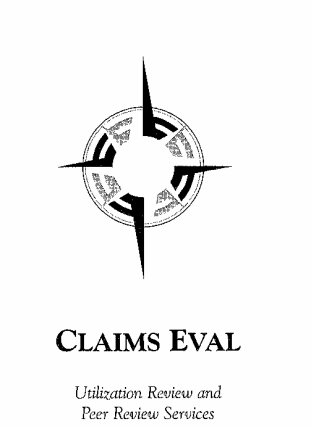

Notice of Independent Review Decision-WC

CLAIMS EVAL REVIEWER REPORT - WC

DATE OF REVIEW: 4-9-09 (AMENDED 4/14/09

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Inpatient lumbar surgery: Examination under anesthesia, lumbar laminectomy, discectomy with L4-L5 and L5-S1 arthrodesis with cages, posterior instrumentation and implantation of a bone growth stimulator at L5-S1 only.

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

American Board of Orthopaedic Surgery-Board Certified

REVIEW OUTCOME

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

☒ Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- DC., office visits from xx-xx-xx through xx-xx-xx (2 visits).
- 9-24-08 MRI of the lumbar spine.
- MD., office visits from 10-7-08 through 2-4-09 (4 visits).
- 10-30-08 EMG/NCS of the upper and lower extremities performed by MD.
- 11-26-08 initial diagnostic pre-surgical screening.
- 3-12-09 MD., performed a Utilization Review.
- 3-19-09 MD., performed a Utilization Review

PATIENT CLINICAL HISTORY [SUMMARY]:

On xx-xx-xx, DC., evaluated the claimant for initial evaluation of the compensable injuries sustained to the cervical spine, thoracic spine, lumbar spine, bilateral hips and head. The claimant reported that he injured himself on xx-xx-xx for working for . He notes that he was stepping onto scaffolding when the board shifted and he fell backwards approximately 5 feet onto the hard floor. He fell flat on his back injuring his head, neck, thoracic spine, back and bilateral hips. The patient was referred to where he was examined, prescribed medication and given some physical therapy. He returned to work on work restrictions, which he has been attempting to perform, but his pain does exacerbate with that. He notes that when he gets home his pain level is dramatically increased and all he does is sleep all night long restlessly because of his pain level. Impression provided included cervical strain-sprain, thoracic sprain-strain, thoracic strain-sprain, lumbar strain-sprain, bilateral SI joint sprain-strain, post concussion syndrome. The evaluator recommended the claimant be off work. Order physical therapy 3 x 4 weeks, request records from. The claimant was given a lumbar brace. The evaluator was referred to Dr. for medication management.

MRI of the lumbar spine dated 9-24-08 showed posterior central disc protrusion measuring 3 mm L4-L5. Posterior central protruded herniated disc measuring 6 mm with thecal sac impingement and annulus tear at L5-S1.

Office visit with Dr. dated 10-7-08 notes the claimant complains of neck pain, bilateral arm pain, low back pain and leg pain after an injury he sustained on the job on 8-22-08. He has undergone conservative treatment over the last 6 weeks and presents for surgical consultation. The claimant had an MRI of the cervical spine and lumbar spine, which was reviewed. He also had x-rays of the pelvis does not show degenerative changes. X-rays of the lumbar spine to include flexion/extension views revealed L4-L5 within normal limits with extension angle measuring 6 degrees, forward flexion 0 degrees with change of 6 degrees, which is within normal limits. At L5-S1 is a grossly unstable with retrolisthesis of 7 mm in extension, which corrects in forward flexion, extension angle measures 25 degrees, which corrects in forward flexion. Physical exam shows paravertebral muscle spasms in the lower cervical and upper thoracic area, and trigger point about his scapular origin bilateral and mid portion trapezius bilaterally. He demonstrates a decreased biceps jerk bilaterally. No gross motor deficits or paresthesias, limitation in range of motion of the cervical spine in extension, positive shoulder abduction test bilaterally. Physical examination of his back and lower extremities reveals positive spring test L5-S1, positive sciatic notch tenderness on the left greater than right, positive extensor lag, positive flip test bilaterally, positive Lasegue's on the left at +45 degrees, contralateral positive straight leg raise on the right at 75 degrees with pain in the back and left lower extremity, absent posterior tibial tendon jerk bilaterally, decreased ankle jerk on the left, paresthesias in the right L5 and S1 nerve root distribution to the left and weakness of gastrocsoleus on the left. The evaluator provided a diagnosis of cervical herniated nucleus pulposus with instability with primary axial symptoms and lumbar herniated nucleus pulposus with instability with both axial and radicular symptoms. The evaluator recommended conservative treatment for at least another 6 weeks. He was continued on Trazadone at night. The evaluator added Ultram for daily pain with Hydrocodone for breakthrough pain and Flexeril for breakthrough muscle spasms. If he fails conservative treatment, then consider epidural steroid injection.

An EMG/NCS of the lower extremities dated 10-30-08 performed by MD., bilateral L5 radiculopathy. NCS showed bilateral internal planter neuropathy. Electrodiagnostic testing of the upper extremity was within normal limits.

Follow-up visit with Dr. dated 11-11-08 notes the claimant had undergone EMG/NCS, which showed bilateral L5 radiculopathy. EMG/NCS of the upper extremities did not show any abnormality. The evaluator reported that the claimant is improving with conservative treatment. The claimant felt that he could tolerate his current symptomatology. Therefore, the evaluator reported the claimant was returned back to Dr. and the claimant will be seen as needed. The evaluator reported the claimant would benefit from a work-conditioning program and retraining.

On 11-26-08, an initial diagnostic pre-surgical screening revealed AXIS I: Adjustment disorder, acute, occupational problem. AXIS II: Deferred. AXIS III: Neck pain, low back pain, thoracic pain, pelvic pain. AXIS IV: Physical health, occupational/work, economic/financial.. Psychosocial stressors are moderate. AXIS V: GAF 55, average 85. The evaluator reported that the claimant has given a good prognosis for surgical

procedure based o the Pre-Surgical and assessment results. His understanding of the medical procedure outcome is deemed realistic. He appears to have an adequate understanding of the surgical procedure to determine that he is currently interested in receiving this treatment as a means of pain relief. His capacities to cope with and comply with requirements/demands recommended by his doctor will require support.

On 12-2-08, Dr. evaluated the claimant. The claimant reported back pain and leg pain present bilaterally, although worse on the left than the right. He also reports neck pain and arm pain. The claimant reports he is no longer willing to put up with current symptomatology. The lumbar spine is bothering him more than his neck. He would like to have surgical intervention. The evaluator recommended surgical intervention.

Follow-up with Dr. dated 12-3-08 notes the claimant continues with complaints of radicular complaint into bilateral posterior pelvis and left hamstring area. The claimant was continued off work. The evaluator reported that the claimant should continue medication management per Dr. The evaluator reported the claimant has decided to progress with surgery.

Follow-up with Dr. on 1-5-09 notes the claimant continues with radicular complaints from the lumbar spine to bilateral pelvis down his left hamstring. The evaluator recommended the claimant would maintain a no work status. The evaluator recommended a Functional Capacity Evaluation.

On 2-4-09, the claimant was evaluated by DC., the claimant was seen for follow up. He evaluator noted the claimant has a Designated Doctor Evaluation scheduled for Friday. The evaluator reported the claimant had a physical permanence examination performed today and hopefully the claimant could move to a work hardening program in the near future.

On 3-12-09, MD., performed a Utilization Review. Peer to Peer performed with Dr.. The reviewer noted he discussed the claimant with Dr. who indicated the claimant had an MRI, which showed disc protrusion and flexion views that showed instability. The claimant was offered steroid, but he refused. Dr. indicated the claimant had had physical therapy. The claimant is a smoker, but not overweight. No additional clinical information provided. The reviewer reported that a very limited clinical picture was submitted. The claimant had substantial amount of psychological issues. The evaluator reported that the claimant had not been referred to pain management for interventional procedures such as lumber epidural steroid injection. The claimant had been cleared from psychiatric standpoint, although there do remain significant psychological factors noted in the notes. The evaluator reported that there was lack of documentation that shows the claimant has failed conservative treatment.

On 3-19-09, MD., performed a Utilization Review. The evaluator reported he was unable to reach Dr. He noted that without benefit of peer discussion and without evidence of progressive neurologic deficit, the reviewer reported he could not

recommend the proposed surgery as medically indicated and necessary without peer discussion or additional records.

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

Following review of the available medical records, I would recommend against surgery with fusion of the lumbar spine. The records demonstrate a lack of application of non-surgical means to manage this injury.

The risk factors of tobacco abuse and psychological conditions has not been addressed and managed. Surgical fusion with these risk factors will likely lead to iatrogenic disability and a chronic pain syndrome.

I have concerns and questions about correlating the mechanism of injury with the alleged injuries of the cervical and lumbar spine. Therefore, non-certification for the proposed surgery.

ODG-TWC, last update 3-17-09 Occupational Disorders of the Low Back – Lumbar Fusion: 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) This study showed that fusion for chronic lower back pain was the least successful common orthopaedic surgery. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. For chronic lower back pain, improvements were statistically significant but clinically negligible. Although pain was reduced and function improved slightly, outcomes remained in the moderately affected range, quality of life was not improved and rendered worse, on average. While surgery for spinal stenosis and for disc herniation compare well with archetypical orthopaedic operations, the outcomes of surgery for chronic lower back pain do not even approach those of other orthopaedic procedures, and the data show that patients with back pain are rendered worse off by surgery. (Hansson, 2008) Recent studies document a 220% increase in lumbar spinal fusion surgery rates, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) 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 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 crtiteria) & 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)

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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**