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Notice of Independent Review Decision

DATE OF REVIEW: 08/19/2008 Amended 8-21-08

IRO CASE #:

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

This case was reviewed by a Orthopaedic Surgery, 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

Remove the hardware at L4-5, then decompress at L5-S1, followed with an ALIF at L5-S1 and a transverse fusion at L5-S1 with 2-3 day length of stay

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 April 2, 2004 CT Scan of the lumbar spine read by Dr.
- o January 21, 2005 X-rays of the lumbar spine read by Dr.
- o February 9, 2005 X-rays of the lumbar spine read by Dr.
- o December 14, 2005 X-rays of the lumbar spine read by Dr.
- o February 21, 2007 MRI of the lumbar spine read by Dr.
- o August 27, 2007 MRI of the lumbar spine, read by Dr.
- o March 3, 2008 X-rays of the lumbar spine, 5 views, read by Dr.
- o March 5, 2008 Initial Chart Note from Dr.
- o April 2, 2008 Chart Note from Dr.
- o April 18, 2008 Psychological Evaluation for discography from Dr.
- o June 23, 2008 Procedure Report for lumbar discography from Dr.
- o June 23, 2008 CT Scan of the lumbar spine read by Dr
- o July 9, 2008 Chart Note from Dr
- o July 16, 2008 Request for Preauthorization for Surgery
- o July 21, 2008 Request for lumbar fusion
- o July 30, 2008 Request for reconsideration for lumbar fusion
- o July 30, 2008 Request for an IRO
- o August 14, 2008 Carrier's response to the disputed services

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records available for my review, the patient is a xx-year-old employee who sustained an industrial injury to the low back on xx.xx.xx when struck in the back and knocked down by a forklift. He has had L4-5 bilateral facetectomy and laminectomy, interbody and posterior fusion on January 5, 2004; hardware removal on July 6, 2004; revision laminectomy and bilateral L5 nerve root exploration, posterior interbody fusion and pedical screws L4-5 on July 12, 2005 and now has chronic radicular pain and failed lumbar surgery.

On April 2, 2004 imaging of CT scan noted a prior fusion at L4-5 with machine bone cages and bone graft, a subtle focal disc protrusion on the right at L5-S1, no evidence of spinal stenosis and a slight degree of spondylolisthesis of L5 with reference to S1. Per MRI of January 21, 2005 the fusion and instrumentation noted on the CT scan was visualized as well as removal of the pedicular screws at L4-5 bilaterally since the CT scan. No recurrence of disc herniation at L4-5 was seen. The central spinal canal, lateral recesses and foramen appeared normal. There is a slight degree of spondylolisthesis of L5 with reference to S1.

A CT Scan of May 9, 2005 indicates a pseudoarthrosis at L4-5 with gas formation. An updated CT Scan of December 14, 2005 shows no evidence of pseudoarthrosis at the L4-5 level. The pedicular screws at that level are in good position.

MRI of February 21, 2007 for back pain extending down the left leg shows intact prior fusion with instrumentation, no evidence of spinal canal stenosis, or lateral recess or foraminal stenosis. No evidence of spondylolisthesis was seen.

Repeat MRI of August 27, 2007 for a patient with low back pain and left leg pain with history of prior fusion in 2004, hardware removal in 2005 and repeat fusion in 2006 shows no significant interval change when compared with the February 21, 2007 exam. There were mild Modic II changes at L4-5 with no marrow edema or fracture. There were multilevel Smorl's nodes. Minimal anterolisthesis was noted of L5 on S1 with mild right more than left facet degenerative changes.

Radiographs of the lumbar spine of March 3, 2008 show disc space narrowing of L3-4 and L5-S1 with normal vertebral body and disc space height. There is no instability on flexion or extension.

The current provider submitted an initial report on March 5, 2008. The patient reports no benefit from surgical interventions of PLIF of L4-5 at the beginning of 2004, hardware removal in July of 2004 and revision fusion in July 2005. His primary concern is low back pain that shoots to the left distal knee with an average pain level of 7/10. He also reports right hip region pain of 5/10 which is symptomatic 6-7 times per year for about 24 hours. He has sleep and sexual function difficulty. He reports moderate help from medications of Hydrocodone, Keppra, Tizanidine and Zolpiderm. He has smoked half a pack per day for the past 5 years. He currently works as a . According to an MRI of August 27, 2007 there is [minimal] anterolisthesis of L5 on S1 as well as facet arthrosis bilaterally, right greater than left at L5-S1. The patient reports epidural injections of August 2004 and April 2006 did not provide any benefit. He underwent discography at L4-5 on November 6, 2003. The patient is tender to palpation on the left with restrictions in range of motion. Reflexes and motor strength are normal. Straight leg is positive on the left.

It was recommended to obtain the discogram and EMG records.

On April 2, 2008 the provider reported that the lumbar discography report of November 2003 showed a normal L3-4. L4-5 had severe concordant pain and L5-S1 was not examined. Recommendation was for repeat discography at L3-4 and testing at L5-S1. The patient underwent psychological evaluation for consideration for discography and surgery on April 18, 2008 and was deemed a successful candidate.

Discogram with CT scan was performed on June 23, 2008. The results state the study is positive for provocation at L5-S1 with excellent concordance and is negative for provocation of pain at L3-4. The CT Scan report states there is an anterior partial annular tear and attempt has been made at discogram at L5-S1 but this apparently was not successful. There was no evidence of disc herniation or foraminal narrowing.

The provider summarized the discography results on July 9, 2008 as follows: At L5-S1 there is presence of gas in the right posterolateral aspect of the disc. Patient had no pain reproduced at L4-5; had 9/10 severe concordant back and left leg pain to the knee reproduced at L5-S1 with pressure of 3-16 psi. Contrast did not remain in the L5-S1 space long enough to be discerned on CT. On examination, there was restriction at end range of motion and pain with extension to the left. Strength and reflexes were normal. Straight leg raise elicited low back pain with radiation to the knee.

Request for anterior interbody fusion, retroperitoneal exposure and discectomy, anterior interbody fusion, posterior decompression, transverse process fusion, posterior internal fixation L5-S1, removal fixation L4-5, bone graft, allograft, autograft in situ, iliac crest, bone marrow aspirate, and Cybertech TLSO with 2-3 days length of stay was not certified in review on July 21, 2008 with rationale that it is unclear that the pain generators in this complicated case involving multiple interventions have been identified. It was noted that MRI of August 27, 2008 shows postoperative changes at L4-5 without abnormal enhancement, minimal anterolisthesis of L5 on S1 and degenerative changes of the facets. Discogram attempt at L5-S1 showed no contrast in the disc. EMG/NCV is mentioned but not available. It is not clear that conservative measures have been exhausted. An attempt to speak with the provider was not realized.

Request for reconsideration for lumbar fusion as described above was not certified in review on July 30, 2008 with rationale that the efficacy of cervical and lumbar spinal fusion is still unproven after over 50 years of clinical practice. The only indications for fusion are instability, tumor and infection. Instability is specifically defined in the guidelines. ODG supports spinal fusion as an option for compression fractures, and specific treatment of spondylolisthesis, documented instability, or post-operative treatment. The requesting physician has failed to demonstrate the presence of lumbar instability. The request is not medically necessary. A TLSO brace was also not certified as braces are not supported by guidelines for prevention of back pain and a surgery request was not certified. A discussion with the provider was attempted but not realized.

On July 30, 2008 the provider requested an IRO.

Per a response letter of August 14, 2008, the carrier does not agree that the requested intervention and procedures are medically necessary because radiculopathy and/or myelopathy have not been demonstrated despite extensive diagnostic testing from 4/2/04 through 6/23/08 or physical examinations, measurable instability has not been established and compression of the L5-S1 disc has not been established.

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

Guidelines do not recommend spinal fusion except when instability has been documented or there is a condition of compression fracture, tumor, infection or significant spondylolisthesis.

The medical records document an intact fusion at L4-5 and minimal anterolisthesis of L5 on S1 with degenerative changes in the facets and normal vertebral body and disc space height and no instability on flexion or extension. The patient has a history of no benefit from surgery, hardware removal intervention, repeat surgery, epidural injections or therapy. He is currently working and continues with low back pain that radiates to the left leg. Reflexes and motor strength are normal. Left straight leg raising is reported as positive without further clarification. EMG/NCV studies have been mentioned but not provided. Discogram at L5-S1 is reported as positive for provocation at L5-S1 with excellent concordance, although post-discogram CT scan noted attempt has been made at discogram at L5-S1 but this apparently was not successful. There was no evidence of disc herniation or foraminal narrowing.

Per the current examination, there is restriction at end range of motion and pain with extension to the left. Strength and reflexes are normal. Straight leg raise elicits low back pain with radiation to the knee. The medical records fail to substantiate radiculopathy either via diagnostic testing or physical examination findings or to demonstrate the presence of lumbar instability that would warrant the requested intervention. Therefore, my recommendation is to agree with the previous non-certification of the request for removal of hardware at L4-5, decompression at L5-S1, followed with an ALIF at L5-S1 and a transverse fusion at L5-S1 with 2-3 day length of 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

The Official Disability Guidelines, Low Back - Lumbar and Thoracic - Spinal Fusion - 8-13-08:

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 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)