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Notice of Independent Review Decision

Date of the Notice of the Decision: 11/4/08
Date of the Notice of the Amended Decision: 11/6/08
Date the Amendment was sent to all parties: 11/6/08

DATE OF REVIEW: 11/04/08

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Item in dispute: Spinal surgery, Cybertech TLSO, Inpatient LOS X 2-3 days 22558, 22585, 64999, 22851, 63047, 63048, 22612, 22614, 22842, 20930, 20936, 20938, 38220, L0637

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

Board Certified Orthopedic Surgeon

REVIEW OUTCOME

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

Denial Upheld

PATIENT CLINICAL HISTORY (SUMMARY):

The employee is a male who was reported to have sustained an injury to his low back on xx/xx/xx. He was reported to have been stepping down from a machine at work and slipped on a step falling backwards catching himself on a railing. The records do not indicate that the employee impacted into the ground but rather jarred his low back.

The submitted clinical records include a preinjury MRI dated 05/18/06. This study reported no significant abnormalities from T12, L1-L3-L4. At L4-L5, there was degenerative hypertrophic spondylosis of the facet joints causing mild bilateral stenosis of the neural foramina and lateral recess with no central canal stenosis. At L5-S1, there was degenerative hypertrophic spondylosis of the facet joints causing bilateral stenosis of the neural foramina and lateral recess. The left neural foramina was more stenotic than the right. There was a broad-based disc bulge present. There was a mild central

canal stenosis present. This study further reported that there was severe disc space narrowing and loss of disc height and endplate degenerative changes at L5-S1.

On 10/26/06, the employee was evaluated by Dr. Dr. noted the above history. She further reported that the employee had a history of low back pain and had a lumbar discectomy and subsequent lumbar epidural steroid injections in 1999. The employee reported that he had been pain free until the recent date of injury. The pain was localized in the low back and radiated down the right leg. The pain was reported to be 10/10, and there was occasional numbness in the right lower extremity. The employee was reported to have previously received two epidural steroid injections in 1992. The past surgical history was positive for right shoulder surgery and lumbar discectomy. Upon physical examination, there was no tenderness in the lumbar paraspinal sacroiliac joint piriformis or trochanteric bursa. Lumbar range of motion forward flexion was 90 degrees, extension was less than 5, and lateral bending was less than 5. He had full range of motion in both the upper and lower extremities. Straight leg raise in the bilateral lower extremities resulted in low back pain. He had a negative Patrick's test and negative Waddell's. Motor strength was 5/5. Sensation was intact to pinprick. He had a negative Hoffman's and no clonus. The employee was diagnosed with low back pain and L5-S1 herniated nucleus pulposus. It was recommended that the employee undergo an EMG/NCV study.

On 11/06/06, the employee underwent an EMG/NCV of the lower extremities to include the lumbar paraspinals and was reported to have findings of peripheral neuropathy on the right and left lower extremities. There was no electrodiagnostic evidence of a lumbar radiculopathy.

The employee was seen in follow-up on 11/27/06. The employee's physical examination was unchanged. The employee was apparently scheduled for lumbar epidural steroid injections.

The employee was subsequently seen in follow-up on 12/12/06. He was reported to be status post an epidural steroid injection on 11/30/06 which helped some and has subsequently been recommended for a second lumbar epidural steroid injection. The employee was continued on oral medications and referred for physical therapy.

The employee was seen in follow-up on 12/27/06. The second epidural steroid injection was denied and physical therapy has also been denied. The employee was continued on oral medications. The employee has requested to be evaluated by a surgeon.

On 02/02/07, the employee was seen at Pain Management; however, this note was incomplete.

The records indicate that the employee underwent diagnostic lumbar medial branch blocks at L5-S1 which were performed on 12/14/07.

The employee subsequently underwent bilateral lumbar facet blocks at L4-L5 and L5-S1 on 03/06/08.

On 08/25/08, the employee was evaluated by Dr. The employee was reported to be a smoker. The employee was noted to have undergone extensive treatment. He reported his left lower extremity became symptomatic five to six months previously with weight bearing. The primary area of pain was in the low back averaging a 5/10 on the visual analog scale. The employee had received five sessions of supervised physical

therapy and reported little or no benefit. It was reported he performed walking at home. He was reported to have a surgical history that was positive for back surgery in 1992 for a herniated disc. He stated that he was able to return to the workforce at less than full functional capability after missing approximately one year. He left that job to work in a field better suited to his functional capabilities. He had repeat surgery on that same disc in 1994 by Dr. The employee reported significant benefit following that procedure and reported being asymptomatic until the date of his most current injury. An MRI of the lumbar spine was reviewed dated 05/18/06. Dr. reported that on his review there were only four motion segments, the lowest space was designated L4-S1. Dr. referenced an IRO decision denying repeat lumbar MRI for the xx/xx/xx date of injury and indicated that the reviewer did not feel a repeat lumbar MRI is indicated; however, it was more appropriately suited for follow-up to the xxxx injury. It was reported that the employee underwent diagnostic lumbar medial branch blocks at L5-S1 and then injections. The employee reported that the injection did not do anything for him. He later underwent medial branch blocks at L4-L5 and L5-S1, and the employee again reported no benefit. Radiographs performed at this office visit indicated atherosclerotic disease, severe disc space narrowing at L4-L5 and L5-S1 with foraminal stenosis or severe disc space narrowing at L4-S1 with foraminal stenosis, four lumbar motion segments and bilateral tropism of the L4, S1 facet complexes. Upon physical examination, the employee could flex to 80 degrees. He had mild difficulty rising. Lateral bending revealed paraspinal spasm on the left. Extension rotation was positive bilaterally, right greater than left, with pain exacerbation of the left low back and left buttocks. Tenderness was mild on the right and exquisite along the midline. There were posterior scars. Upon physical examination, deep tendon reflexes were intact at the knees and ankles. Straight leg raise was positive on the left with pain in the low back. Lasegue's is negative. Motor strength was graded as 5/5 with the exception of left EHL which was graded as 4/5. Dermatomal pattern revealed no paresthesias. Dr. Henderson recommended the employee undergo ALIF with interbody fixation at L4-S1 with decompression and transverse process fusion.

The employee was subsequently referred for psychiatric evaluation on 09/22/08. This submitted report was incomplete and cut off at page four, and therefore, the evaluator's determination was not noted.

On 09/29/08, the request for surgery was reviewed by Dr. Dr. recommended against operative intervention. He noted that there was no instability noted. There was no frank radiculopathy, and therefore, opined that the employee did not meet criteria under the ***Official Disability Guidelines***.

On 10/07/08, the case was reviewed by Dr. Dr. recommended against operative intervention. He reported that the employee had a remote history of lumbar surgery. He indicated that preinjury, the employee had degenerative changes noted on MRI. He further reported no instabilities documented on flexion extension films, and there was no clear-cut evidence of radiculopathy. He further referenced a peer review which opined that the employee's conditions were preexisting.

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

I would concur with the two previous reviewers in that based upon the submitted clinical information, the requested operative intervention, the Cybertech TLSO and Inpatient LOS x 2-3 days is not in accordance with the ***Official Disability Guidelines***. It was noted that the employee had a history of two previous back surgeries and had clear

evidence of degenerative changes at L4-L5 and L5-S1 prior to his compensable event. Records indicate that the employee had minimal conservative therapy in regard to physical therapy. The employee has undergone medial branch blocks and facet blocks with no improvement. His social history indicates that he is a smoker. The employee had no electrodiagnostic evidence of a lumbar radiculopathy as of 11/06/06. He has evidence of peripheral neuropathy in the bilateral lower extremities but clearly no evidence of a lumbar radiculopathy.

The employee was subsequently referred to Dr. The employee has undergone flexion extension radiographs which revealed no evidence of instability. The employee's physical examination was more remarkable for posterior element pain. The employee was reported to have low back pain with radiation into the left lower extremity and was opined to have a positive straight leg raise, and there was some reported weakness graded 4/5 in the left EHL. However, these findings were not consistent with the previous electrodiagnostic studies or reports.

It was further noted that the employee was appropriately referred for psychiatric preoperative psychiatric evaluation; however, the complete report was not available for review and was limited through page four.

Therefore, it would be my opinion that the employee is not a surgical candidate and would not meet criteria under current evidence-based guidelines for the proposed anterior lumbar interbody fusion at L4-S1 with decompression and transverse process fusion with instrumentation. It is also my opinion that the Cybertech TLSO and Inpatient LOS x 2-3 days would not meet criteria under current evidenced-guidelines.

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

The *Official Disability Guidelines*, 11th Edition, The Work Loss Data Institute.

Fusion (spinal)	<p>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) (Devo-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.</p>
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([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. ([Devo-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 discectomy. [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](#))