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IRO REVIEWER REPORT

DATE OF REVIEW: 07/09/07

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Items in Dispute: L5-S1 PLIF/fusion with instrumentation.

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

Texas License and currently on TDI DWC ADL.
Board Certified Neurosurgeon

REVIEW OUTCOME:

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

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

1. MRI lumbar spine dated 09/08/05.
2. Employer's First Report of Injury or Illness.
3. MRI lumbar spine dated 06/13/06.
4. Medical records Dr. dated 07/16/06 – 10/28/06.
5. Electrodiagnostic study dated 10/25/06.
6. Treatment records D.C., dated 11/03/06 – 03/26/07
7. Medical records Dr. dated 12/04/06 – 05/21/07.
8. Peer review dated 12/25/06.
9. Medical records Dr. dated 01/05/07.
10. Peer review dated 02/02/07.
11. Procedure report dated 02/22/07.
12. Medical Records Dr. dated 04/24/07.
13. Peer review dated 05/04/07.
14. Medical Records Dr. dated 05/13/07.

INJURED EMPLOYEE CLINICAL HISTORY (SUMMARY):

The employee is a male who was reported to have sustained injuries to his trunk and low back as a result of a slip and fall.

The employee sought care from D.C. and was subsequently referred for MRI of the lumbar spine on 09/08/05. This study reported a loss of disc hydration at L4-5 and L5-S1. There was a central focal disc protrusion with increased signal in the protruding disc indicative of tears within the annular fibers. In addition, there was bilateral facet arthrosis and narrowing of the neural foraminal canal at this level. Plain x-rays obtained on this date indicated a transitional vertebra with lumbarization of the S1 segment.

The employee was subsequently referred for a second MRI on 06/13/06. This study reported facet arthrosis at L2-3, L3-4, and L4-5 and noted a 6 mm central disc protrusion contributing to moderately severe canal stenosis at the origin of the S1 nerve roots bilaterally.

The employee was seen by Dr. on 07/16/06. At that time, the employee was reported to have back pain with intermittent right sided L5 radiculitis without signs of neurological or root compression. The employee was reported to have been placed under symptomatic treatment aside from physical therapy, and the employee reported progressive improvement. His neurologic examination revealed that the employee was ambulatory. Thoracolumbar range of motion was adequate in all directions. He remained free of any focal objective motor or sensory deficits. He was advised to continue a home low back exercise as well as continue oral medications. The employee was allowed to work in a modified duty capacity.

When seen in serial follow up on 08/27/06, the employee was reported to have continued to improve with no change in his physical examination. The employee indicated that he was performing regular activity despite having work restrictions. The employee again was reported to have improved with conservative care.

On 11/03/06, the employee sought care from D.C. This note suggests that the employee had significantly exacerbated. His physical examination was certainly aberrant from the previous examinations. The employee was reported to have severely diminished lumbar range of motion in all planes. He was reported positive for heel walk, positive for toe walk. Straight leg raising was reported to be positive. Braggart's test was reported to be positive. The bowstring test was reported to be positive. Milgram's test was reported to be positive. Galenson's, Naclus, Eli's and Ericson's tests were reported to be positive. On palpation, the employee was reported to have lower lumbar hypertonicity bilaterally with tenderness to palpation over the L4-5 and L5-S1 segments.

The employee was subsequently referred to Dr. on 12/04/06. The employee was reported to have undergone an EMG/NCV study by Dr. which was reported as normal. The employee reported stiffness in the morning to his back, weakness in his left leg. He experienced some tingling and giving away symptoms in the left leg. On physical examination, he had mild tenderness to the paravertebral muscles. No spasm was noted. Forward flexion and lateral bending were adequate. There was decreased sensation along the lateral aspect of the left foot. Reflexes were 2+ and symmetrical. X-rays of the lumbar spine showed multilevel degenerative changes. The employee was recommended to be referred to Dr. for epidural steroid injections.

The employee was seen by Dr. on 01/05/07. The employee’s physical examination is largely normal. The employee was reported to have a positive straight leg raise at 30 degrees on the left resulting in diminished sensation and strength. The employee was recommended to undergo epidural steroid injection along with be referred for an EMG/NCV study. The employee eventually underwent a transforaminal epidural steroid injection on 02/22/07. The available medical record indicate that the employee had fairly consistently reported left lower extremity symptoms. He underwent two epidural steroid injections with no sustained relief.

The employee later came under the care of Dr. Dr. note dated 04/24/07 indicated that there was no weakness or sensory deficit in the upper extremities. There were normal deep tendon reflexes. Motor strength in the lower extremities was reported to be 4/5 in the right dorsiflexors and 5/5 on the left. He reported decreased deep tendon reflexes and decreased sensation to soft touch. Dr. opined that the employee had failed conservative care and recommended operative intervention. He had recommended that the employee undergo a PLIF at L5-S1.

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

The request for PLIF at L5-S1 with instrumentation is not considered medically necessary. The available medical record indicates that the employee has inconsistent symptoms and has been evaluated by numerous providers who either find no evidence of radiculopathy or suggest evidence of a radiculopathy in the left lower extremity. Subsequently the employee most recently has been found to have normal function in the left lower extremity and abnormalities in the right lower extremity. Given that the employee has not undergone a preoperative psychiatric evaluation and his clinical presentation is ambiguous and the origins of the employee’s pain have not been conclusively identified, the request for operative intervention cannot be considered medically necessary at this time.

Citation:
ODG

Fusion (spinal)	
<p>Not recommended for patients who have less than six months of failed conservative care unless there is 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 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 recommended conservative therapy. 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, but 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) Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and</p>	

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](#)) ([Atlas, 2006](#)) Despite poorer outcomes in workers’ compensation patients, utilization is much higher in this population than in group health. ([Texas, 2001](#)) ([NCCI, 2006](#)) 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](#)) Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis may be candidates for fusion. ([Eckman, 2005](#)) 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 demanding surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. ([van Tulder, 2006](#)) ([Maghout, 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. Also predictors 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 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](#)) 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](#)) 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](#)) 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.

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 unilateral neural arch hypoplasia. (2) Segmental Instability - 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. (3) Primary Mechanical Back Pain/Functional Spinal Unit Failure, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability, with and without neurogenic compromise. 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. (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.

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion 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-ray demonstrating spinal instability and/or MRI, Mylogram or CT discography 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](#))

If the IMED's decision is contrary to: (1) the DWC's policies or guidelines adopted under Labor Code §413.011, IMED must indicate in the decision the specific basis for its divergence in the review of medical necessity of non-network health care or (2) the networks treatment guidelines, IMED must indicate in the decision the specific basis for its divergence in the review of medical necessity of network health care.

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

A. Official Disability Guidelines