



IMED, INC.

1701 N. Greenville Ave. • Suite 202 • Richardson, Texas 75081
Office 972-381-9282 • Toll Free 1-877-333-7374 • Fax 972-250-4584
e-mail: imeddallas@msn.com

DATE OF REVIEW: 11/15/07

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

An L4-L5 TLIF-PISP and three (3) day inpatient stay.

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

Texas License
Board Certified Orthopedic Surgeon

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. Employer's First Report of Injury or Illness.
2. thru 06/23/05 –Centers.
3. 07/26/05 thru 08/29/06 –Medicine.
4. 07/26/05 – X-ray report from Medicine.
5. 07/28/05 – MRI of the lumbar spine.
6. 08/17/05, 09/28/05, 11/14/05 – Procedure reports.
7. 09/06/05, 12/01/05, 04/19/07, 07/17/07 –M.D., reports.
8. 11/13/05, 01/06/06 – Peer reviews by M.D.
9. 11/14/05 – Discogram.
10. 12/28/05 –URA.
11. 01/25/06 –Insurance letter to designated doctor.
12. 01/31/06 – Designated Doctor Evaluation by M.D.
13. 03/24/06 –Corporation Functional Capacity Evaluation.
14. 12/08/06 thru 10/12/07 –Medicine Center.
15. 03/27/07 – Discogram.
16. 04/10/07 – Designated Doctor Evaluation report by Dr..

17. 06/11/07 –Diagnostic laboratory report.
18. 06/21/07 –Associates, URA denial.
19. 08/21/07 –Associates, URA denial.
20. 09/10/07 – Psychological examination by Dr..
21. ***Official Disability Guidelines.***

PATIENT'S CLINICAL HISTORY (SUMMARY)

The employee was injured while employed as a . The employee seated in a pickup truck that was stopped at a traffic light when a Cargo van slammed into the rear end.

The employee experienced low back pain and went to Medical Centers for evaluation. Dr. found symmetrical reflexes, strength, and sensation in the bilateral lower extremities and negative straight leg raising. The employee did have low back pain and was referred for physical therapy and given medications.

Dr., an orthopedic spine surgeon, examined the claimant on 07/26/05. Dr. noted mild paraspinal muscle spasm, left greater than right, and restricted range of motion in the lumbar spine. Reflexes, strength, and sensation were physiologic in the bilateral lower extremities. Straight leg raising was negative. Dr. recommended a lumbar MRI.

A lumbar MRI was performed at MRI on 07/28/05. The radiologist reported a predominantly central and right paracentral and right foraminal broad-based disc protrusion at L4-L5 with associated slight elevation of the posterior longitudinal ligament. There was no spinal stenosis. There was early degenerative change within the L4-L5 disc. There was mild facet joint arthropathic changes at L4-L5 and L5-S1 with no significant hypertrophy.

Dr. referred the employee for epidural steroid injections.

Dr. performed the first of three epidural steroid injections on 08/17/05.

On 08/30/05, Dr. noted that the first epidural steroid injection had caused a significant increase in the bilateral lower extremity pain, and the pain in the lumbar spine had not decreased. The employee was taking Vicodin for pain.

The employee received a total of three injections that may have helped temporarily.

A CT/discogram was performed by Dr. at Hospital on 11/14/05. The CT reported disruption of the fibers at L4-L5 along the right paraspinous region with a contrast extravasation in the posterior epidural space on the right paraspinal region. There was degenerative disc disease at L5-S1 without significant spinal canal stenosis.

Dr. requested precertification for an arthrodesis at L4-L5 including a transforaminal intervertebral fusion and a posterolateral internal fixation arthrodesis.

Dr. repeated the discogram on 03/27/07. The doctor reported a normal L3-L4 disc with an injection of 1.5 cc of Omnipaque 300. At L4-L5, 2 cc of Omnipaque was injected resulting in a spongy end point. The pain response was 4/4 with concordant low back pain. The contrast passed into the epidural space on the right. At L5-S1, again 2 ml of Omnipaque was injected and passed into the epidural space. The employee again had concordant low back pain.

Dr. performed a Designated Doctor Evaluation on 04/10/07 and found that the employee was not at Maximum Medical Improvement (MMI) because he needed to have surgery. The physical examination included a normal neurological examination and negative straight leg raising.

Dr. examined the employee on 04/19/07 and noted low back pain and diffuse leg pain that was 8/10. Dr. reported symmetrical reflexes, strength, and sensation with normal toe and heel walking. Straight leg raising was negative. The employee was subjected to a blood test to detect nicotine. He had quit smoking, and there was no nicotine detected.

On 07/06/07, Dr. noted that the employee had low back pain with numbness, tingling, and burning in both legs. The employee was neurologically intact with negative straight leg raising.

Dr., a psychologist, performed an evaluation on 09/10/07 and concluded that the employee was psychologically stable and was capable of making an informed decision concerning his surgical procedure.

Official Disability Guidelines:

Fusion (spinal)	Not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "Patient Selection Criteria for Lumbar Spinal Fusion," after 6 months of conservative care. 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. 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)
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([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. ([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, 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](#)) 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](#)) Lumbar spinal fusion surgeries use bone grafts, and are sometimes

combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurological deficits.

Lumbar fusion in workers' comp patients: In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, and this treatment for this condition remains "under study." It appears that workers' compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. ([Fritzell-Spine, 2001](#)) ([Harris-JAMA, 2005](#)) ([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](#)) ([Devo, 2005](#)) ([LaCaille, 2005](#)) ([Trief-Spine, 2006](#)) Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. ([LaCaille, 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](#)) ([Devo-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](#))

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 (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced

	<p>segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical disectomy. (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. (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.</p> <p>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)</p>
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ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION.

The clinical results of lumbar arthrodesis are problematic in that many surgeries are performed without an accurate diagnosis of the pain generator. **Official Disability Guidelines** recommend consideration of arthrodesis for excessive motion, spondylitic spondylolisthesis, neural arch defects, traumatic spondylolisthesis, or other instabilities due to fracture or dislocation. The employee meets none of these criteria. He has mechanical low back pain that has not improved with conservative care. The diagnostic studies are equivocal in that the MRI found a protrusion to the right side, which is opposite to the initial pain complaint. The discogram reported concordant pain at L4-L5 and L5-S1, although the CT scan again found some extravasation to the right rather than the left. One of the most telling features of this history is that the first epidural steroid injection caused increased pain in the back. This finding mitigates against a conclusion of a discogenic pain generator. It is certainly possible that the injection was performed improperly. However, with the documented utilization of fluoroscopy, that occurrence is unlikely. The injection of Bupivacaine and steroid into the epidural space will almost always reduce the inflammatory effect of proteoglycans being expressed from a damaged disc. In the absence of such improvement, one must question the diagnosis of discogenic pain.

The employee has been neurologically intact from the beginning as documented by multiple credible examiners. He does not meet requirements for a simple discectomy, laminectomy, or facetectomy. The employee does not have any instability due to either trauma or degenerative changes that would provide indications for an extensive lumbar arthrodesis. The procedure would be doomed to failure.

Therefore, this appeal is denied.

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

1. ***Official Disability Guidelines***