



## IMED, INC.

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### Notice of Independent Review Decision

**DATE OF REVIEW:** 11/12/07

**DATE OF AMENDED REVIEW:** 12/17/07

**IRO CASE #:**

### **DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

A 360 degree fusion at L4-L5 and L5-S1.

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

Texas License  
Board Certified Neurological Surgeon  
Board Certified Orthopedic Physician

### **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. EMG/NCV study dated 11/01/05.
2. MRI lumbar spine dated 10/06/05.
3. Medical records Dr. dated 07/05/06 thru 08/14/06.
4. CT/myelogram 07/05/06.
5. Designated Doctor Evaluation, Dr. dated 12/15/05.
6. Medical records Dr.
7. MRI cervical spine dated 02/28/07.
8. MRI lumbar spine dated 02/28/07.
9. Lumbar myelogram dated 09/13/07.
10. ***Official Disability Guidelines.***

### **PATIENT'S CLINICAL HISTORY (SUMMARY)**

The employee is a xx year old female who is reported to have sustained multiple injuries as a result of a slip and fall occurring on xx/xx/xx.

The employee is currently under the care of Dr.. The request is for medical necessity of a 360 degree fusion at L4-5 and L5-S1. The available medical record indicates that the employee was employed in a sedentary position and while at work on the date of injury she slipped on some water. She presented to the emergency room at on xx/xx/xx with complaints of right wrist, right elbow, low back and coccyx pain. X-rays performed in the emergency room of the right elbow, pelvis and right wrist were reported to be normal. The sacrum and coccyx films reported findings suggestive of an anterior subluxation of the coccyx.

The employee was later seen by Dr. who performed a series of trigger point injections and referred the employee to physical therapy. The employee subsequently was recommended to undergo imaging studies.

The record indicates that the employee was later referred to Dr., a neurologist, on 10/04/05. Dr. notes indicate that the employee was previously seen approximately two years earlier for almost the same complaints following an automobile accident. The employee reports that these symptoms resolved within months. An MRI of the cervical spine revealed straightening of the cervical lordosis but no significant pathology and the employee's complaints were reported to be chronic.

The employee later came under the care of Dr. who recommended that the employee receive conservative care.

The employee was also seen by Dr., and there was a recommendation for operative intervention.

A Designated Doctor Evaluation report dated 12/16/05 found the employee to be at clinical Maximum Medical Improvement (MMI). Upon examination, the employee was reported to have evidence of tenderness to palpation in the lumbar paraspinal musculature, gluteal musculature. The spine is of normal alignment with no asymmetry. Range of motion was abnormal with pain noted on all ranges. Dr. found the employee to be at clinical MMI with 0% impairment. The records further included electrodiagnostic studies performed on 11/01/05. These studies were reported to indicate a possible S1 radiculopathy; however, I would note that none of the paraspinal musculature was tested, and therefore, this test is inconclusive.

The record includes a letter dated 01/26/07. At that time, Dr. noted that the employee's diagnosis is a chronic pain syndrome and myofascial pain syndrome. She reports that her conclusions are the same. She indicates that the employee has subjective complaints of pain along with her physical findings and the multitude of diagnostic testing performed which do not correlate. She notes there

was not one focal neurologic deficit in either the upper or lower extremities based on symptomatology and physical examination. Therefore, the consideration of cervical interventions based on radiographic findings alone without physical exam correlation or subjective complaints correlation is at a significant risk of failure and is not indicated.

The employee subsequently came under the care of Dr. on 01/12/07. At that time, the employee reported significant low back pain with radiation into the lower extremities. On physical examination the employee has reported to have no clear cut weakness in the upper or lower extremities. Her Achilles reflex is depressed on the left hand side. There was no weakness in the upper or lower extremities. She ambulates with a slight antalgic gait. Straight leg raising produces spasm on the left hand side at 40 degrees. Dr. reports dated imaging studies and reports that the employee has a herniated disc at L5-S1 on the left hand side. Dr. recommends that the employee undergo new imaging studies. MRI of the cervical spine was performed. This will not be addressed. MRI of the lumbar spine performed on 02/28/07 indicates mild broad based disc bulge causing mild encroachment upon the anterior aspect of the dural sac and neural foramina. The facet joints are maintained. A L5-S1 there is asymmetrical bulging of the disc noted centrally and to the left of midline causing mild to moderate encroachment upon the central and left anterolateral aspect of the dural sac and inferior recess left neural foramen. The right neural foramen and facet joints are maintained. The employee was subsequently recommended to undergo lumbar discography which does not appear to have been performed.

On 06/25/07, the employee was informed that a minimally invasive microdiscectomy at L5-S1 would be the most likely procedure to offer pain relief and improvement. On 08/18/07 the employee is reported to be worse. The employee is reporting worsening symptoms with increased weakness and numbness. The employee was recommended to undergo CT myelography. This study was performed on 09/13/07. The myelogram indicated mild wasting of the contrast column at L5-S1 with mild wasting at L4-L5. The disc space was narrowed at L4-L5 and L5-S1. There was no gross evidence for nerve root sleeve amputation with mild irregular contour of the L4 and L5 nerve root sleeves. The post procedure CT indicates moderate facet hypertrophy and ligamentum flavum thickening at L3-4 with mild degenerative disc disease and minimal disc bulge. There is mild left and right foraminal narrowing. At L4-5 there was a broad-based disc bulge centrally and to the left of midline. There was facet hypertrophy and ligamentum flavum thickening. These findings together produce mild to moderate spinal stenosis and bilateral foraminal narrowing. At L5-S1 there is disc vacuum phenomenon with no disc bulge plus osteophyte. There was moderate facet disease as well. There was no spinal stenosis. There was bilateral foraminal narrowing.

Dr. has requested that the employee undergo a 360 degree two level fusion at L4-L5 and L5-S1.

Citation:  
ODG

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. 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 <a href="#">conservative therapy</a>. [For spinal instability criteria, see AMA Guides (<a href="#">Andersson, 2000</a>)] For complete references, see separate document with all studies focusing on <a href="#">Fusion (spinal)</a>. 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. (<a href="#">Gibson-Cochrane, 2000</a>) (<a href="#">Savolainen, 1998</a>) (<a href="#">Wetzel, 2001</a>) (<a href="#">Molinari, 2001</a>) (<a href="#">Bigos, 1999</a>) (<a href="#">Washington, 1995</a>) (<a href="#">DeBarard-Spine, 2001</a>) (<a href="#">Fritzell-Spine, 2001</a>) (<a href="#">Fritzell-Spine, 2002</a>) (<a href="#">Deyo-NEJM, 2004</a>) (<a href="#">Gibson-Cochrane/Spine, 2005</a>) (<a href="#">Soegaard, 2005</a>) (<a href="#">Glassman, 2006</a>) (<a href="#">Atlas, 2006</a>) 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.” (<a href="#">Resnick, 2005</a>) (<a href="#">Fritzell, 2004</a>) 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. (<a href="#">Airaksinen, 2006</a>) For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. (<a href="#">Ivar Brox-Spine, 2003</a>) (<a href="#">Keller-Spine, 2004</a>) (<a href="#">Fairbank-BMJ, 2005</a>) (<a href="#">Brox, 2006</a>) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. (<a href="#">Bagnall-Cochrane, 2004</a>) (<a href="#">Siebenga, 2006</a>) 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. (<a href="#">Wickizer, 2004</a>) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. (<a href="#">Weiner-Spine, 2004</a>) (<a href="#">Shah-Spine, 2005</a>) (<a href="#">Abelson, 2006</a>) 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</p>
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	<p>consensus on the appropriate indications for performing spinal fusion. (<a href="#">Deyo-Spine, 2005</a>) (<a href="#">Weinstein, 2006</a>) Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (<a href="#">van Tulder, 2006</a>) (<a href="#">Maghout-Juratli, 2006</a>) Despite the new technologies, reoperation rates after lumbar fusion have become higher. (<a href="#">Martin, 2007</a>) 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. (<a href="#">CMS, 2006</a>) 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. (<a href="#">Burnett, 2006</a>) 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. (<a href="#">Hallett, 2007</a>) 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.</p> <p><u>Lumbar fusion in workers' comp patients:</u> 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. (<a href="#">Fritzell-Spine, 2001</a>) (<a href="#">Harris-JAMA, 2005</a>) (<a href="#">Maghout-Juratli, 2006</a>) (<a href="#">Atlas, 2006</a>) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. (<a href="#">Texas, 2001</a>) (<a href="#">NCCI, 2006</a>) 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. (<a href="#">DeBerard-Spine, 2001</a>) (<a href="#">DeBerard, 2003</a>) (<a href="#">Deyo, 2005</a>) (<a href="#">LaCaille, 2005</a>) (<a href="#">Trief-Spine, 2006</a>) Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. (<a href="#">LaCaille, 2007</a>)</p> <p><u>Lumbar fusion for spondylolisthesis:</u> 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. (<a href="#">Eckman, 2005</a>) 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</p>
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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](#)) 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](#))

**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 disectomies on the same disc, fusion may be an option at the time of the third disectomy, which should also meet the ODG criteria. (See [ODG Indications for Surgery -- Disectomy.](#))

**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)

	<p>X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see <a href="#">discography criteria</a>) &amp; MRI demonstrating disc pathology; &amp; (4) Spine pathology limited to two levels; &amp; (5) <a href="#">Psychosocial screen</a> 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. (<a href="#">Colorado, 2001</a>) (<a href="#">BlueCross BlueShield, 2002</a>)</p>
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**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION.**

The request for 360 degree fusion at L4-L5 and L5-S1 is not supported by the submitted medical documentation. The available medical records indicate that the employee has undergone extensive conservative care for an injury to her low back. The serial records indicate that the employee's imaging studies, symptoms and subjective reports do not correlate. While the record indicates that the employee clearly has completed conservative care consisting of oral medications, physical therapy, interventional procedures and time, there would be no indication based on the available record for a 360 degree fusion. The available records do not include any flexion or extension films which would indicate that the employee has any instability at these levels. It is further noted that there is no evidence on CT or MRI of spondylosis or spondylolisthesis. The employee does have some areas of stenosis noted at L4-5 and L5-S1 which is very mild in nature and does not closely correlate with her reported symptoms. The employee has undergone CT myelography which indicates no significant obstructive lesions and I would further note that the employee has not undergone a detailed psychological evaluation which is mandated by the Official Disability Guidelines before the consideration of a lumbar fusion. Therefore, it is my opinion that the requested 360 degree two level fusion at L4-L5 and L5-S1 is not medically necessary at this time.

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

1. ***OFFICIAL DISABILITY GUIDELINES***