

# Clear Resolutions Inc.

An Independent Review Organization  
7301 RANCH RD 620 N, STE 155-199A  
Austin, TX 78726  
Phone: (512) 772-4390  
Fax: (512) 519-7316  
Email: resolutions.manager@cri-iro.com

## NOTICE OF INDEPENDENT REVIEW DECISION

**DATE OF REVIEW:**

Apr/21/2009

**IRO CASE #:**

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

Arthrodesis, Anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression) thoracic

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

M.D., Board Certified Orthopedic Surgeon

**REVIEW OUTCOME:**

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

Upheld (Agree)

Overturned (Disagree)

Partially Overturned (Agree in part/Disagree in part)

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

ODG Guidelines and Treatment Guidelines

MRI thoracic spine, 05/15/07

Office notes, Dr. , 06/02/08, 06/16/08, 08/04/08, 08/14/08, 10/27/08, 01/21/08, 01/23/09

MRI lumbar spine, 06/11/08

MRI thoracic spine, 06/11/08

Addendum, 06/11/08

IME, Dr. , 07/23/08

DDE, Dr. , 08/20/08

Discogram, 11/14/08

CT thoracic spine, 11/14/08

Office note, Dr. , 02/13/09

Psychiatric evaluation, 02/16/09

Request for surgery, 02/26/09

Adverse Determination Letters, 03/02/09, 03/24/09

## **PATIENT CLINICAL HISTORY SUMMARY**

This is a xx year-old male claimant who slipped and fell on his back on xx/xx/xx. He had immediate mid back pain and his low back and bilateral lower extremities became symptomatic approximately 3 months post injury. It was noted that EMG/NCV studies on 10/08/07 showed narrowed interspace at L5-S1 with definite right sided sacralization and a question of a pars defect on the left; mobile retrolisthesis at L4-5 which was above the intercrestal line. A thoracic MRI on 05/14/07 showed a 2 millimeter central disk protrusion with mild central canal stenosis at T6-7. He was noted to be a smoker.

Dr. saw the claimant on 06/02/08 with primary thoracic pain, low back pain, bilateral lower extremity pain with pain from the buttocks to the arch of the foot posteriorly and somewhat laterally despite therapy, work hardening, a home exercise program, medications, sacroiliac (SI) joint injections, median branch blocks and radiofrequency neurotomy. Lumbar x-rays that day showed narrowed interspace at L5-S1 with definite right side sacralization, question of pars defect on the left and mobile retrolisthesis at L4-5 which was above the intercrestal line. The examination showed moderate difficulty rising, paraspinal spasm on the right with lateral bending, positive extension and rotation bilaterally greater on the left with pain reproduction in the mid and low back. Rib compression test was positive with pain in lateral rib cages bilaterally greater on the right. Straight leg raise was positive bilaterally, greater on the left with pain exacerbation in the mid and low back. He had hyperesthesia (tingling) on the right from the knee to the great toe medially and laterally from the ankle to the foot, excluding the 5th toe; representative of nerve root distributions of L4 and S1. Thoracic syndrome with a herniated nucleus pulposus from T6-7; lumbar radicular syndrome; 4 mobile lumbar segments; sacralized L5-S1 and possible unilateral pars defect on left at L5-S1 were diagnosed. A lumbar MRI on 06/11/08 showed mild degenerative disc disease at L4-5 and L5-S1 without significant canal stenosis. There was mild foraminal stenosis bilaterally at L4-5. A thoracic MRI that day was normal. Dr. reviewed the lumbar MRI and stated it was normal except for facet hypertrophy at L4-5 and L5-S1 which may be symptomatic. He stated that the thoracic MRI showed decreased T2 signal intensity at T10. He apparently was given facet injections into the low back on 07/21/08.

Dr. performed an independent medical evaluation on 07/23/08 and indicated that the claimant had received multiple injections including facet injections, right piriformis muscle and medial branch nerve blocks with perhaps 50 percent improvement. He reported upper back, intermittent low back pain with standing and constant right leg pain with numbness. He was noted to be slightly overweight. There was generalized right low back and mid thoracic spine tenderness, tenderness of the right sciatic notch and limited motion attributed to voluntary restriction. Straight leg raise on the right was positive to 60 degrees causing right hip and low back pain which was increased with plantar flexion of the foot causing radiation of pain down right leg, which is not physiologic. Waddell tests were all inappropriate. Patellar and Achilles reflexes were 1+ and equal. He had stocking decreased sensation about the right thigh. Probable thoracolumbar strain without radiculopathy was diagnosed. Dr. stated that no further treatment was necessary including medications, that he had been overtreated, could return to full duty without restrictions, had reached maximum medical improvement with 0 percent impairment rating and that there was absolutely no indication for surgery or other treatment.

The 08/04/08 visit noted mid back, right lower extremity pain to the lateral aspect of the thigh from the hip to the knee and in the instep of the right foot with low back pain. The examination noted reduced forward flexion, paraspinal spasms on right lateral bending, extension and rotation continued to be symptomatic bilaterally, but pointed to the mid back as the area of pain exacerbation.

There was moderate tenderness bilaterally in the mid back most significantly around the thoracolumbar junction and over lower segments of the lumbar spine. Straight leg raise changed somewhat as there was pain exacerbation bilaterally, greater on the right with pain in the buttocks ipsilateral to the right. He had decreased sensitivity on the left from the distal thigh to the instep of the left foot and numbness on the right lateral ankle and foot, along L3, L4 and S1 nerve root distributions. Dr. recommended that the radiologist re-review the MRI

from 06/11/08. The re-read was interpreted by Dr. to be normal. He agreed with the normal signals on T2 weighted sagittal views.

Dr. sated on 08/20/08 that the claimant had not reached maximum medical improvement. A discogram of T9-10 on 11/14/08 showed no pain, only a pressure sensation at T9-10. Morphologically there was normal bilocular disc. At T10-11 he had 20 out of 10 pain in the midline thoracic spine which radiated upwards which was concordant with his usual pain. Morphologically there was a grade II-III posterior fissure. The CT showed no grossly abnormality in the thoracic paraspinous soft tissues. He was not able to quit smoking. Dr. saw the claimant again on 01/23/09 for low and mid back pain, bilateral heel pain, greater on the left. The examination noted him to flex to 10 degrees. Lateral bending showed poor motion bilaterally and paraspinal spasms on the right. Extension with rotation was positive on the right with pain in the mid low back. He had tenderness of the thoracic and lumbar spine and winced with palpation of paraspinal muscles. Straight leg raise and Lasegue's were negative. The dermatomal pattern was numb at the left medial lower leg from the knee to ankle and laterally along the ankle and foot with numbness on the right at the medial aspect of the foot and great toe. An interbody fusion from T10-11 was recommended.

A psychological evaluation on 02/16/09 indicated that the claimant appeared very capable of working with Dr. in considering and pursuing surgery. The fusion was denied twice and is currently under dispute.

#### **ANALYSIS AND EXPLANATION OF THE DECISION INCLUDING CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION**

This is a 38-year-old male who has had an independent medical evaluation on 07/23/08 that demonstrates significant Waddell's signs. The MRI of the thoracic spine on 05/15/08 demonstrates a disc protrusion at T6-T7. An MRI of the lumbar spine on 06/11/08 demonstrates no neural compressive lesion. There is a discogram on T9-T10 that demonstrates pain at T10-11 at 20 out of 10 where as at T9-T10 no pain whatsoever. There is questionable merit of the interpretation of the discography. There is no instability, tumor, or infection noted at this level. Based upon these medical records surgery is not indicated. This determination is consistent with the ODG. The reviewer finds that medical necessity does not exist for Arthrodesis, Anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression) thoracic.

Official Disability Guidelines Treatment in Worker's Comp 2009 Updates, (i.e. Low Back-Fusion)

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) (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) This study showed that fusion for chronic lower back pain was the least successful common orthopaedic surgery. The study

compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. For chronic lower back pain, improvements were statistically significant but clinically negligible. Although pain was reduced and function improved slightly, outcomes remained in the moderately affected range, quality of life was not improved and rendered worse, on average. While surgery for spinal stenosis and for disc herniation compare well with archetypical orthopaedic operations, the outcomes of surgery for chronic lower back pain do not even approach those of other orthopaedic procedures, and the data show that patients with back pain are rendered worse off by surgery. (Hansson, 2008) Recent studies document a 220% increase in lumbar spinal fusion surgery rates, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) 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)

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

[ ] ACOEM-AMERICA 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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)