

I-Decisions Inc.

An Independent Review Organization

71 Court Street

Belfast, Maine 04915

(207) 338-1141 (phone)

(866) 676-7547 (fax)

Notice of Independent Review Decision

DATE OF REVIEW: JANUARY 2, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Transforaminal lumbar interbody fusion with pedicle screw fixation at L5-S1 using neuroplasty

A 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

Employer's report, 05/15/05

Office note, , PA, 05/16/05

Office note, MD, 05/19/05

Chiropractic note, 05/24/05

X-rays lumbar spine, 05/24/05

MRI lumbar spine, 05/31/05

Office note, Dr., 06/06/05, 06/15/05, 06/22/05, 06/28/05

Office note, Dr., 06/09/05

Operative report, 06/15/05

EMG, 06/15/05

Digital myelography, 06/22/05

Office note, Dr., 07/08/05
Office note, Dr., 09/30/05
Letter, 10/20/05, 03/24/06
Office note, Dr., 11/14/05, 12/12/05, 02/01/06, 03/01/06, 03/16/06, 03/27/06, 03/31/06,
04/26/06, 09/13/06
Lumbar myelogram/CT, 12/12/05
Office note, Dr. , 12/20/05
FCE, 01/06/06, 07/27/06
Office note, Dr., 01/24/06, 03/30/06, 05/16/06, 06/30/06, 07/25/06, 09/06/06, , 02/27/07,
04/04/07,
MRI lumbar spine, 02/21/06
Peer review, 03/01/06
Office note, , 04/26/06
Office note, Dr. i, 06/13/06, 07/20/06
Operative report, 07/06/06, 10/13/06
Hand-written notes, 09/03/06
Medical Evaluation, Dr., 09/12/06
Consent, 09/18/06
Office note, 10/11/06, 12/12/06
Pre-op H & P, 10/12/06
Medication, 10/17/06
X-ray lumbar spine, 12/12/06
Muscle testing, 01/03/07, 03/14/07, 06/06/07, 09/12/07
Medial and psych evaluation, 03/13/07
Office note, Dr., 04/11/07
Office note, Dr., 04/19/07, 10/08/07
Office note, Physical medicine, 05/02/07, 05/09/07, 06/06/07, 07/03/07, 07/18/07,
08/15/07, 09/12/07
Medical evaluation, 08/14/07
Office note, Dr., 08/18/07
Peer review, 10/09/07, 10/30/07
Office note, Dr., 10/24/07
Psych evaluation, 11/09/07
Physical performance evaluation, Health Care System, 11/09/07
ODG Guidelines

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a xx year old female, employed as a at the time of her injury on xx/xx/xx when she slipped and hit her head on a box. The initial diagnosis was lumbar contusion and strain and treatment included activity modification, chiropractic therapy and medications. Lower back and left lower extremity pain and symptoms persisted. The impression was lumbar radiculopathy and the claimant was referred to pain management.

Lumbar CT myelogram on 06/22/05 noted an annular bulge at L4-5 and a three to four millimeter posterocentral disc protrusion at L5-S1 with mild indentation in the thecal sac. Pain and left lower extremity numbness and weakness persisted despite several injections and therapy. Subsequently on 07/06/06, the claimant underwent left hemilaminectomy and left partial facetectomy at L5-S1, lateral recess decompression and excision of protruding disc, L5-S1 discectomy, spinal cord and L5-S1 nerve root decompression, and exploration of epidural space.

The claimant continued with progressive worsening of lower back pain and left leg pain, weakness and numbness. She underwent four trigger point injections and an epidural block with only partial and temporary relief. Flexion /extension lumbar films on 12/12/06 noted L5-S1 disc degeneration with limited lumbar motion. No spondylosis was noted and vertebral heights were maintained. The claimant underwent medical and psychological evaluation and was deemed a candidate for a functional restoration program.

Dr., spine surgeon, saw the claimant on 04/19/07. Lumbar motion was limited with muscle motor testing to both lower extremities intact. Sensation was decreased in the left lateral thigh and with the exception of the bilateral posterior tibialis reflex, which was absent, reflexes were intact. The impression was failed L5-S1 discectomy, mechanical back pain and left leg radiculopathy. Electrodiagnostic studies on 08/18/07 noted evidence of bilateral L5 lumbosacral radiculopathy, both acute and chronic. Lumbar fusion was proposed.

The most recent clinical examination was from 10/24/07 with Dr.. He noted an antalgic gait favoring the left side with moderate to severe parathoracic, paralumbar and paragluteal myospasticity, right greater than left with hypesthesia in L4-5 and L5-S1 on the left. Sitting straight leg raise was positive on the left. The diagnosis was lumbar discitis, left sacroiliac joint dysfunction, status post L5-S1 discectomy and depression. Fusion surgery was again recommended. A psychological evaluation on 11/09/07 noted no barriers to the proposed plan of treatment. Psychotherapy sessions were recommended for chronic pain management. The claimant's weight was noted to be 220 pounds.

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

The claimant is a xx-year-old woman who has had ongoing back complaints following a xx/xx/xx injury. She underwent multiple diagnostic studies showing a very small disc protrusion at L5-S1. She was treated conservatively with ongoing pain, and on 10/13/06 underwent an L5-S1 disc excision. She continued to have pain complaints, and the medical record does not document neurologic abnormality. There is no documentation in the medical record of structural instability, recurrent disc herniation, or documented neurologic abnormality on physical examination. An L5-S1 lumbar fusion has been requested.

I do not see the medical indication for the requested lumbar fusion. There was no documentation of a postoperative infection, recurrent disc herniation, structural instability, or other progressive loss of function. There is no documentation in this medical record of a specific reason why this requested lumbar disc fusion would change this person's ongoing complaints. Therefore, I do not see the medical indication for this requested operative procedure.

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. (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) 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) (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) (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) 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) (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 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- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGBASE**

- 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)**