

I-Decisions Inc.

An Independent Review Organization

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Notice of Independent Review Decision

DATE OF REVIEW:

AUGUST 6, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Arthrodesis, anterior interbody technique, including minimal discectomy to repair interspace with a three day length of stay

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

Lumbar spine MRI, 05/30/06

Office note, Dr. 01/23/07

Office notes, Dr. 02/26/07, 04/23/07 and 06/07/06

Lumbar myelogram, 04/28/07

Post myelogram CT scan, 03/28/07

Lumbar review, 06/10/07 and 06/18/07

Office note, Dr. 06/25/07

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a female technician who tripped over a cable and landed on her buttocks and then on her back. The MRI of the lumbar spine showed narrowing of the left neural foramen caused by diffuse bulging of the intervertebral disc and hypertrophic bony spurs and no spinal stenosis at L2-3. At L3-4, there was spinal stenosis with an AP dimension of 7 millimeter caused by a combination of bulging disc and hypertrophy of the facet joints. There was narrowing of the left neural foramen and no disc herniation. At L4-5 disc, there was mild spinal stenosis caused by diffuse bulging of the intervertebral disc without focal herniation. The AP dimension of the spinal canal measured 10 millimeter. The 01/23/07 electromyography revealed abnormal prolonged distal tibial H reflex latency bilaterally. This suggested a bilateral S1 radiculopathy. The prolonged sural latencies bilaterally indicated probable trauma or entrapment of these nerves at the ankle. The slowing was seen in the right tibial nerve between the knee and the ankle indicated probable trauma or entrapment of this nerve in the lower leg. All of these values were normal. There was no additional evidence of a radiculopathy.

The claimant saw Dr. on 02/26/07 for complaints of constant low back and bilateral leg pain. The claimant also noted the pain radiates to her knees bilaterally and has intermittent numbness and tingling that went down to the top of her feet bilaterally. The claimant had been treated with Prozac, Lortab and physical therapy. Dr. noted that the claimant had been placed at maximum medical improvement with 0% impairment rating. Dr.'s review of the MRI on 05/30/06 was that it showed decreased signal intensity at the lower four intervertebral disc spaces and type II Modic changes at L2-3 and L5-S1. Both of the spaces were markedly narrowed. Lumbar L3-4 and L4-5 had good alignment. Dr. felt that there was significant spinal canal stenosis at L4-5 and narrow foramina at L2-3 as well as L5-S1. The AP diameter at L3-4 was 7 millimeter and 10 millimeters at L4-5. Dr. also reviewed the plain films on 05/30/06 which showed retrolisthesis of L2 on L3 and a narrowed disc space with sclerosis around the end plates. There was good maintenance of disc space at L3-4 and L4-5 severely narrowed interspace at L5-S1, facet narrowing, facet hypertrophy, facet arthrosis and sclerosis around the L5-S1 endplates. Examination revealed motor and reflexes were intact. Extension and rotation revealed marked decreased range of motion resistance and pain reproduced bilaterally. The claimant had limited lumbar range of motion. Diagnosis was multiple level spondylosis at L2 to L5, marked disc resorption at L2-3 and L5-S1 with severe spondylosis, central canal stenosis at L3-4 and L4-5 and lumbar radicular syndrome. Dr. recommended a lumbar myelogram with flexion and extension views.

The 03/28/07 post myelogram CT showed mild retrolisthesis at L2-3 and associated with a left paracentral disc protrusion encroaching on the left lateral recess. There was mild retrolisthesis at L2-3 associated with left paracentral disc protrusion encroaching on the left lateral recess. Mild L3-4 central spinal canal stenosis with AP diameter of the thecal sac of 9 millimeter was present. Mild central spinal stenosis at L4-5 due to diffuse disc bulging as well as facet hypertrophy and ligamentum flavum thickening was noted.

Dr. evaluated the claimant on 04/23/07. Dr. reviewed the 03/28/07 lumbar CT and felt that it showed at L2-3, a 3-4 millimeter of retrolisthesis, mild facet arthropathy, and a left paracentral disc protrusion at 4 millimeter. At L3-4, she has 3 millimeter posterior annular bulge, mild facet hypertrophy and central spinal canal stenosis with AP diameter of 9 millimeter. At L4-5, there was significant posterior disc bulge, moderately severe central spinal stenosis as well as significant lateral recess stenosis at L5, bilateral and

severe osteoarthritis at L5-S1. The most significant stenosis was at L3-4, L4-5. Dr. recommended a four level discogram L2-3, L3-4, L4-5 and L5-S1 without sedation which was denied by the carrier.

The claimant saw Dr. on 06/07/07 for complaints of severe pain and difficulty with activities of daily living. The claimant was taking 4 Vicodin daily. Dr. recommended to wean off Vicodin and a four level anterior posterior fusion with decompression at L3, L4 and L5 and transverse process fusion from L2 to S1. The claimant saw Mr. psychologist, on 06/25/07. Mr. supported her emotionally for the surgical intervention; however, he noted that she would still face some very significant vocational issues which were going to compound her depression and anxiety.

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

Request for arthrodesis anterior interbody technique including minimal discectomy to repair interspace with 3 day length of stay does not appear to be medically necessary and reasonable in this female. It should be noted that she has had back pain predominantly with much or lesser leg pain. She has had physical therapy, TENS, massage. She's been taking Lortab, Prozac. MRI demonstrates no spinal stenosis, no disc herniation. EMG demonstrates no evidence of radiculopathy. There is notably suggestion of sural nerve entrapment at her ankles however. She does have on 3/28/07 a mild retrolisthesis on L2-3 and it appears that this is a degenerative segment. There is no evidence in any documentation that she has instability of her spine. There is no evidence per history that she has had a history of trauma or on her advanced imaging tests. There is no evidence that she has had any evidence of tumor in her lumbar spine as well. She has been seen by the psychologist due to the medicines and Trazadone abuse, Wellbutrin and Vicodin were noted. Given the diagnosis of discogenic back pain and based upon the natural history of this diagnosis, fusion is not recommended. It is unclear why all of these levels have been requested. Radiographs do not demonstrate spinal instability. Guidelines would recommend that fusion be limited to two levels. It is unclear whether or not this patient smokes and if so, there should be a period of cessation. Based upon all of this information, I do not think it is reasonable to proceed with the above-mentioned procedure.

Official Disability Guidelines Treatment in Workers' Comp 2007 Updates, Low back 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. 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. 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 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. For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis may be candidates for fusion. In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. 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. The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. 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. Outcomes from demanding surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. 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. 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. 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. Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. 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). 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. 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. Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. 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. Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion.

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 - Spondylytic 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 disectomy. (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, Myelogram or CT discography demonstrating disc pathology; & (4) Spine pathology limited to two levels; & (5) 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 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 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)