

November 17, 2006

TX DEPT OF INS DIV OF WC
AUSTIN, TX 78744-1609

CLAIMANT: ___

EMPLOYEE: ___

POLICY: M2-07-0266-01

CLIENT TRACKING NUMBER: M2-07-0266-01

Medical Review Institute of America (MRIOA) has been certified by the Texas Department of Insurance as an Independent Review Organization (IRO). The Texas Department of Insurance Division of Workers Compensation has assigned the above mentioned case to MRIOA for independent review in accordance with DWC Rule 133 which provides for medical dispute resolution by an IRO.

MRIOA has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed. Itemization of this information will follow.

The independent review was performed by a peer of the treating provider for this patient. The reviewer in this case is on the DWC approved doctor list (ADL). The reviewing provider has no known conflicts of interest existing between that provider and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent, or any of the treating doctors or insurance carrier health care providers who reviewed the case for decision before referral to the IRO.

Records Received:

RECORDS RECEIVED FROM THE STATE:

Notification of IRO Assignment dated 10/26/06, 12 pages

RECORDS RECEIVED FROM ROBERT MYLES, MD:

Radiology reports, 4/11/05,4/22/05, 2 pages

Lumbar spine MRI report, 4/28/05, 2 pages

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Letter from Dr. Harmon to Dr. Myles dated 5/18/05, 1 page
Orthopedic Institute of Texas report dated 5/19/05, 4 pages
Patient information sheet, 1 page
Accident details, subrogation form, 5/19/05, 6 pages
Office notes, Dr. Myles, 6/2/05, 6/21/05, 6/23/05, 7/6/05, 7/28/05, 6 pages
Electrodiagnostic Studies dated 7/09/05, 2 pages
Texas Workers Comp Work Status report, 3 pages
Intracorp denial letter dated 8/4/05, 3 pages
Notes from Orthopedic Institute of Texas, 8/8/05, 10/4/05, 1/3/06, 2/23/06, 7/26/06, 9/20/06
10 pages
2nd opinion from Kirk Harmon DC, 10/4/05, 1 page
Surgical order sheet, 1 page
Surgery verification sheet, 1 page
Preauthorization form, 2 pages
Fax coversheet from Intracorp dated 10/12/05, 1 page
Peer to peer telephone call sheet, 2 pages
Letter from Dr. Myles dated 10/14/05, 1 page
CT discogram, 11/14/05, 4 pages
Operative report, 11/14/05, 6 pages
Letter from Intracorp dated 11/29/05, 1 page
Designated doctor evaluation from Dr. Douglas, 12/19/05, 11 pages
Financial policy, 2 pages
Preauthorization form, 1 page
Intracorp letter dated 1/10/06, 3 pages
Letter from Dr. Myles dated 1/27/06, 1 page
Radiology report 1/27/06, 1 page
Intracorp letter dated 2/3/06, 3/28/06, 6 pages
Letter dated 8/14/06, 2 pages

RECORDS FROM ACE/ESIS/CIGNA:

Letter from ESIS dated 11/1/06, 1 page
Concerta medical records, 3/11/05, 3/15/05, 3/17/05, 3/22/05, 4/1/05, 4/6/05, 13 pages
Work status reports, 8 pages
Main Street Chiropractic Clinic notes, 5/31/05, 2 pages
New patient history and physical Precision Pain Management, 8/2/05, 3 pages
Letter dated 10/14/05 from Dr. Myles to ESIS, 1 page
Functional Abilities Evaluation, 10/26/05, 14 pages
Letter from Dr. Capello dated 10/26/05, 12 pages
Anesthesia record 11/14/05, 1 page

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Dispute of Designated Doctor Impairment Rating dated 2/13/06, 2 pages

Designated Doctor Evaluation dated 5/8/06, 8 pages

Main Street Chiropractic notes 4/11/05–6/19/06, 26 pages

Summary of Treatment/Case History:

The patient is a 42 year old male who is reported to have sustained an injury to his low back on _____. The available record indicates that the patient initially sought care from Kirk Harmon, D.C.

The patient was referred for MRI of the lumbar spine on 04/27/05. This study, interpreted by Darrell Hobson, D.C., reports mild grade I spondylolytic spondylolisthesis of L5 associated with a 3 mm broad based right paracentral disc protrusion with mild narrowing of the right exit neuroforamen. There is mild intervertebral osteochondrosis at L4–5 with a 2 mm posterior annular bulge and a small annular fissure/tear. There is further identified a 2 mm posterocentral disc protrusion with thecal effacement at L2–3.

The patient was referred to Dr. Robert Myles on 05/19/05. At this time the patient reports low back pain with radiation into the right lateral thigh and left posterior thigh. His back pain is reported to be greater than his leg pain. The patient is reported to have tried chiropractic treatments and passive modalities, and has not had an exercise program. On physical examination the patient is reported to have mildly reduced lumbar range of motion. His lower extremity motor strength is rated as 5/5. Knee and ankle reflexes are 2+ and symmetric. The patient is reported to have a positive straight leg raise bilaterally and decreased sensory perception in the right lateral thigh. The patient is diagnosed with an acquired spondylolisthesis, placed on oral medications and referred for physical therapy. The patient was referred for electrodiagnostic testing on 07/09/05. At this time it is reported that the patient has findings consistent with a right L5 radiculopathy. On 10/04/05 Dr. Myles requested to perform an ALIF at L4–5 and L5–S1.

The patient was referred for lumbar discography on 11/14/05. The patient is reported to have concordant pain at L2–3, L3–4, L4–5 and L5–S1. The patient is reported to have nonconcordant pain at L1–2 with abnormal disc morphology noted at this level.

The patient was evaluated by Designated Doctor, Howard Douglass on 12/19/05. At this time Dr. Douglass notes the history above. On examination the patient has tenderness over the lumbar spine from L1 through L5 with no evidence of any paravertebral muscle spasm. The sitting root test is positive bilaterally. The supine straight leg test is reported to be positive bilaterally. The sitting straight leg raise is negative bilaterally. The patient is reported to have normal sensation in the L4, L5 and S1 dermatomes. The patient's reflexes are reported to be normal and symmetric. The patient's lower extremity motor strength is reported to be intact. Dr. Douglass opines that the patient has reached MMI on 12/19/05 and assesses the patient with a 5% whole person impairment

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rating. The patient was referred for flexion/extension films and is reported to have 6 cm of anterior translation from flexion to extension with a retrolisthesis of L4 and L5 of approximately 5 mm. The record indicates that the patient has received continued conservative care, and numerous requests have been placed to perform an anterior and posterior fusion at L4–5 and L5–S1.

Questions for Review:

Date of Injury ___

1. Please review denied pre-authorization request for anterior lumbar fusion L4–S1 with posterior instrumentation.

Explanation of Findings:

1. Please review denied pre-authorization request for anterior lumbar fusion L4–S1 with posterior instrumentation.

The request for anterior lumbar fusion L4–S1 with posterior instrumentation is not medically necessary. The available clinical record indicates the patient has undergone extensive conservative care for low back pain and has electrodiagnostic evidence of a right L5 radiculopathy. However, clearly there is significant conflicting data in the available medical record. Several providers do not objectively appreciate the right L5 radiculopathy on examination. The patient has previously been evaluated by a designated doctor, who by law is a disinterested party, who found no evidence of lower extremity radiculopathy as reported on previous physical examinations and suggested by electrodiagnostic studies. Further, the record indicates that the patient has undergone lumbar discography and he has abnormal disc morphology at 5 levels. The patient has been recommended to undergo a 2 level fusion which would not take into account the other levels of degenerative disc disease. It is suggested that the patient has significant lumbar instability at L4–5, L5–S1 which potentially could benefit from a stabilization procedure; however, it is unlikely that this procedure in itself would eliminate the patient’s back pain considering the results of the lumbar discogram. The record does not contain preoperative psychological evaluation or assessment.

Conclusion/Decision to Not Certify:

The proposed request for anterior lumbar fusion L4–S1 with posterior instrumentation is not medically necessary.

Applicable Clinical or Scientific Criteria or Guidelines Applied in Arriving at Decision:

The Official Disability Guidelines report “Not recommended for workers’ compensation patients in the absence of spinal fracture, dislocation, spondylolisthesis if there is instability, and selected other conditions outlined below. In cases other than workers’ comp, after screening for biopsychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease after at least 6 months of conservative therapy. There is limited scientific

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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." (Resnick, 2005) (Fritzell, 2004) 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) 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) Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis may be candidates for fusion. (Eckman, 2005) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. (Bagnall-Cochrane, 2004) 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) 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) Workers' compensation has been associated with especially poor outcomes after surgery. (Harris-JAMA, 2005) Outcomes from demanding surgical fusion techniques are no better than the traditional posterolateral fusion without internal fixation. (van Tulder, 2006) Presurgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers' compensation

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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. (DeBerard–Spine, 2001) (DeBerard, 2003) (LaCaille, 2005) (Trief–Spine, 2006) A major study is underway which aims to identify characteristics that result in better patient selection for surgery. (Deyo, 2005) 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. (Carragee, 2006) 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.

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 or dislocation. Indications for spinal fusion may include: 1) Neural arch defect – Spondylolytic spondylolisthesis, congenital unilateral neural arch hypoplasia. 2) Segmental Instability – Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability. 3) Primary Mechanical Back Pain/Functional Spinal Unit Failure (in cases other than workers’ comp). 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 Required:

Pre–operative clinical surgical indications for spinal fusion include all of the following: 1) All pain generators are identified and treated; and 2) All physical medicine and manual therapy interventions are completed; and 3) X–ray demonstrating spinal instability and/or MRI or CT discography demonstrating disc pathology; and 4) Spine pathology limited to two levels; and 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)

Bambakidis et al reports, “In cases of progressive neurologic deterioration or in the presence of mild to moderate myelopathy and concordant radiographic abnormality, the neural elements should be decompressed. Decompression may be accompanied by appropriate fusion, instrumentation, or both when instability or spondylolisthesis is documented radiographically. In the absence of neurologic deficits but in the presence of a concordant radiographic cause of symptoms,

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decompression should be considered if conservative management fails. The indications for surgical intervention become less clear in patients with mechanical pain without a significant radiographic abnormality. In such cases, discography may be considered for localization of the painful motion segment, although its use remains controversial. Conservative therapy is the treatment of choice in these patients. However, surgical fusion may be considered in select individuals after careful consideration of additional psychosocial factors that could contribute to their pain. Such patients must understand that the likelihood of achieving a pain-free outcome is low”.

References Used in Support of Decision:

1. S. Terry Canale, MD, Campbell's Operative Orthopedics, 10th edition University of Tennessee-Campbell Clinic, Memphis TN, Le Bonheur Children's Medical Center, Memphis, TN ISBN 0323012485
2. The Official Disability Guidelines, 11th edition, The Work Loss Data Institute. Accessed: 11/15/2006.
3. Nicholas C. Bambakidis, MD, Iman Feiz-Erfan, MD, Jeffrey D. Klopfenstein, MD, and Volker K. H. Sonntag, MD. Indications for Surgical Fusion of the Cervical and Lumbar Motion Segment. Spine 2005; 30: S2-S6.

The physician who provided this review is a fellow of the American Board of Orthopaedic Surgery. This reviewer is a fellow of the North American Spine Society and the American Academy of Orthopaedic Surgeons. This reviewer has been in active practice since 1990.

Your Right To Appeal:

If you are unhappy with all or part of this decision, you have the right to appeal the decision. The decision of the Independent Review Organization is binding during the appeal process.

If you are disputing the decision (other than a spinal surgery prospective decision), the appeal must be made directly to a district court in Travis County (see Texas Labor Code §413.031). An appeal to District Court must be filed not later than 30 days after the date on which the decision that is the subject of the appeal is final and appealable.

If you are disputing a spinal surgery prospective decision, a request for a hearing must be in writing and it must be received by the Division of Workers' Compensation, Chief Clerk of Proceedings, within ten (10) days of your receipt of this decision.

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A copy of this decision should be attached to the request. The party appealing the decision shall deliver a copy of its written request for a hearing to all other parties involved in the dispute

In accordance with Division Rule 102.4(h), I hereby verify that a copy of this Independent Review Organization (IRO) Decision was sent to the carrier, the requestor and claimant via facsimile or U.S. Postal Service from the office of the IRO on this 15 day of Nov/2006.

Stacie Sterken

MRIOA is forwarding this decision by mail, and in the case of time sensitive matters by facsimile, a copy of this finding to the treating provider, payor and/or URA, and the DWC.

It is the policy of Medical Review Institute of America to keep the names of its reviewing physicians confidential. Accordingly, the identity of the reviewing physician will only be released as required by state or federal regulations. If release of the review to a third party, including an insured and/or provider, is necessary, all applicable state and federal regulations must be followed.

Medical Review Institute of America retains qualified independent physician reviewers and clinical advisors who perform peer case reviews as requested by MRIOA clients. These physician reviewers and clinical advisors are independent contractors who are credentialed in accordance with their particular specialties, the standards of the American Accreditation Health Care Commission (URAC), and/or other state and federal regulatory requirements.

The written opinions provided by MRIOA represent the opinions of the physician reviewers and clinical advisors who reviewed the case. These case review opinions are provided in good faith, based on the medical records and information submitted to MRIOA for review, the published scientific medical literature, and other relevant information such as that available through federal agencies, institutes and professional associations. Medical Review Institute of America assumes no liability for the opinions of its contracted physicians and/or clinician advisors. The health plan, organization or other party authorizing this case review agrees to hold MRIOA harmless for any and all claims which may arise as a result of this case review. The health plan, organization or other

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third party requesting or authorizing this review is responsible for policy interpretation and for the final determination made regarding coverage and/or eligibility for this case.

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Case Analyst: Stacie S ext 577