

April 14, 2006

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

CLAIMANT: \_\_\_

EMPLOYEE: \_\_\_

POLICY: M2-06-0926-01

CLIENT TRACKING NUMBER: M2-06-0926-01

AMENDED REVIEW 4/19/06 JC

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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, 3/13/06 - 2 pages
- Medical Dispute Resolution Request/Response, 3/13/06 - 3 pages
- Table of Disputed Charges, undated - 1 page
- Denial Letter, 1/13/06 - 1 page
- Denial Letter, 1/31/06 - 1 page
- Surgery Preauthorization, 12/30/05 - 1 page

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Records Received from the Respondent:

- Letter from Flahive, Ogden, and Latson to MRloA, 3/21/06 - 2 pages
- Letter from Flahive, Ogden, and Latson to MRloA, 3/9/06 - 2 pages
- Duplicates, various dates - 7 pages

Records from Requestor:

- Physical Examination, 7/29/04-8/4/04 - 4 pages
- ROM Testing, 8/3/04 - 6 pages
- Spinal Sonography, 8/4/04 - 2 pages
- Electrodiagnostics, 8/4/04 - 4 pages
- Office Notes, 8/5/04-8/13/04 - 3 pages
- ROM Testing, 8/11/04 - 6 pages
- X-Rays, 8/23/04 - 1 page
- Office Notes, 8/18/04-10/11/04 - 12 pages
- Consultation from Spine Associates, 8/31/04 - 2 pages
- MRI Reports, 8/31/04 - 1 page
- Office Notes from Spine Associates, 9/7/04 - 2 pages
- ROM Testing, 9/24/04 - 13 pages
- Letter to Insurance from Page W. Nelson, MD, 10/19/04 - 7 pages
- Office Notes from Spine Associates, 10/19/04 - 1 page
- Follow-Up Consultation Notes, 10/24/05-11/21/05 - 4 pages
- Office Notes, 10/11/04-2/1/06- 12 pages
- Letter from Spine Associates to Debra Perry, DC, 1/18/05 - 1 page
- Office Notes from Spine Associates, 1/18/05 - 2 pages
- Letter from Spine Associates to Debra Perry, DC, 2/1/05 - 1 page
- Office Notes from Spine Associates, 2/1/05 - 2 pages
- FCE, 6/16/05 - 14 pages
- Office Notes from Spine Associates, 6/23/05 - 2 pages
- Letter to Insurance from Douglas M. Stauch, MD PA, 7/8/05 - 9 pages
- Office Notes from Spine Associates, 8/13/05 - 1 page
- Initial Examination Report, 9/2/05 - 4 pages
- Office Notes from Spine Associates, 12/20/05-2/7/06 - 4 pages
- Exercise Flow Sheet, 3/21/06-3/23/06 - 2 pages
- Rehab Notes, 9/2/04 - 1 page
- Texas Workers' Compensation Work Status Report, 8/6/04-4/1/06 - 23 pages
- Duplicates, various dates - 9 pages

**Summary of Treatment/Case History:**

This is a 37 year old male who sustained a worker's compensation injury on \_\_\_\_\_. He was working as a mechanic and was pushing multiple cars and developed stabbing low back pain. He initially received chiropractic treatment which was unsuccessful. He had electrodiagnostic studies that revealed no abnormalities. He had an MRI that showed degenerative disk at L5 with an annular tear and a 4-5 mm central-left disc protrusion. He has not responded to conservative treatment since the

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date of injury and it is now proposed to surgically implant a prosthetic disk and treat postoperatively with cryotherapy for analgesia.

**Questions for Review:**

Pre authorization request: Application, intervertebral biomechanical device(s) to vertebral defect/interspace (artificial disc replacement L5/S1) Cryo unit x 10 days.

**Explanation of Findings:**

Pre authorization request: Application, intervertebral biomechanical device(s) to vertebral defect/interspace (artificial disc replacement L5/S1) Cryo unit x 10 days.

The proposed procedure does not meet criteria for medical necessity at this time. This is in regard to prosthetic intervertebral disk replacement. If the surgery is not done, then there would be no need for cryotherapy.

The summary of the current literature reveals mixed results as far as spinal disk replacement is concerned. There is no evidence in the current literature that spinal disk replacement is superior to fusion. There is also no evidence in the current literature that documents why degenerative disk disease is a pain generator in some people and yet remains asymptomatic in many others. This calls into question whether the diagnosis of pain caused by disk degeneration is accurate. Although the FDA approved spinal disk replacement in 2004, the procedure remains controversial, and there is a lack of well designed studies and long-term results. References included in the bibliography contains reference to numerous complications which in some cases, are life threatening. Also, revision of artificial disk replacement is quite risky. The overall failure rate of these devices within less than five years is over 30%.

The Technology Evaluation Center report is a series of technology evaluations based on evidence based medicine. The case for lumbar fusion and for lumbar disk replacement as a treatment for degenerative disk disease remains controversial and is far from proven. There is no convincing evidence in this particular case based on the history and physical findings that the fifth lumbar disk as the cause of this particular patient's pain. He has normal electrodiagnostic studies and findings on MRI that are, common in both symptomatic and asymptomatic patients. He also has a normal neurologic examination. The FDA approval carried with it a requirement for a randomized double blinded study with five year results regarding artificial disk replacement and this study has not yet been completed.

**Conclusion/Decision to Not Certify:**

The proposed procedure is not medically necessary.

**References Used in Support of Decision:**

1. Proposed decision memo for lumbar artificial disc replacement (C AG 00292N) from the Centers for Medicare and Medicaid Services, 2/15/06, accessed online
2. Technology Evaluation Center, Volume 20, No 1, April 2005

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The physician providing this review is board certified in Orthopedic Surgery. The reviewer holds additional certification from the American Board of Orthopaedic Surgery. The reviewer has served in capacity of executive committee member, credentials committee, chairman of the surgery department, board of directors and quality boards at various hospitals and medical centers. The reviewer currently serves as the Chief of Orthopedic Surgery at a VA Medical Center. The reviewer has been in active practice since 1970.

#### 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.

Chief Clerk of Proceedings / Appeals Clerk  
P. O. Box 17787  
Austin, TX 78744

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. MRIOA is forwarding this decision by mail, and in the case of time sensitive matters by facsimile, a copy of this finding to 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

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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 MRloA harmless for any and all claims which may arise as a result of this case review. The health plan, organization or other 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: Jamie C ext 583

Cc: requestor and respondent