

MCMC

IRO Medical Dispute Resolution M2 Prospective Medical Necessity IRO Decision Notification Letter

Date:	04/06/2006
Injured Employee:	
Address:	
MDR #:	M2-06-0963-01
DWC #:	
MCMC Certification #:	IRO 5294

REQUESTED SERVICES:

Please review the item(s) in dispute: Inpatient total disk arthroplasty L4-5 with Charite artificial disk and two day inpatient length of stay.

DECISION: **Upheld**

IRO MCMCllc (MCMC) has been certified by the Texas Department of Insurance as an Independent Review Organization (IRO) to render a recommendation regarding the medical necessity of the above disputed service.

Please be advised that a MCMC Physician Advisor has determined that your request for an M2 Prospective Medical Dispute Resolution on 04/06/2006, concerning the medical necessity of the above referenced requested service, hereby finds the following:

Inpatient total disk arthroplasty L4-5 with Charite artificial disk and two day inpatient length of stay is not medically necessary.

CLINICAL HISTORY:

The 58-year-old female allegedly fell on _____. She has complained of low back pain and left hip pain. The MRI of 06/11/2003 revealed an acute or subacute compression fracture at L2, left disc protrusion with osteophytes at L4/5 and L5/S1. A bone density study on 12/15/2003 was essentially normal. She was evaluated by Dr. Buch for a mass on her back. He was unable to find anything.

The myelogram CT scan of 01/12/2004 revealed multilevel degenerative disease in the lumbar spine with varying degrees of foraminal stenosis. There was the chronic compression fracture of the inferior end plate of L2 that produced mild canal stenosis. The osteophytes at multiple levels produced secondary foraminal stenosis.

Dr. Wharton evaluated her on 02/12/2004 and recommended an osteoplasty rather than a kyphoplasty for the compression fracture. Dr. W injected cement into the L2 vertebra under general anesthesia (GA) on 02/23/2004. The injured individual however continued to complain of low back pain and Dr. Wharton recommended a discogram CT scan. The injured individual continued to complain of pain and claimed that all her symptoms began from the date of alleged injury. She had a Designated Doctor Evaluation (DDE) by Dr. Steel. On 05/17/2004 she received sacroiliac (SI) joint injections but did not have any benefit from this.

Another DDE on 01/31/2005 agreed with the recommendation of Dr. Wharton to obtain a discogram study. The injured individual in the meantime continued to receive physical therapy (PT), medications, and chiropractic care. Another DDE was performed by Dr. Steel on 08/19/2005. The injured individual continued to complain of low back pain with intermittent radiation of pain with numbness to the right lower extremity. On examination she had no objective clinical findings of nerve root tension or spinal instability. Her ROM was limited secondary to pain. Once again a discogram study was recommended. An Independent Medical Exam (IME) by Dr. Stetzner recommended a discogram study.

REFERENCE:

Edward N. Hanley, Jr. Surgical Stabilization of the Spine Improved Disability Slightly More Than an Intensive Rehabilitation Program in Patients with Chronic Low Back Pain. J Bone Joint Surg. AM., Feb 2006;88:453.

RATIONALE:

A discogram CT scan of 10/14/2005 revealed a concordant back pain at L3/4, L4/5 and L5/S1. All three discs were opacified with evidence of facet arthrosis at all levels. On 10/18/2005 Dr. Wharton noted that the injured individual had “disruptive patterns” with concordant pain at the three levels tested. She also had a retrolisthesis at L2/3 just below the vertebral body that had been filled with cement. Based on this Dr. Wharton recommended disc replacement “probably most specifically at L5/S1”.

The recommendations made by Dr. Wharton are not in keeping with standard of care based on scientific rationale. To begin with the result of the discogram lack validity and reliability since there was no pain free level. Therefore the result of the discogram failed to establish the need for any operative treatment.

Leaving aside the issue of the inappropriateness of using the results of discogram study in this injured individual, it would not be considered appropriate to recommend any type of invasive treatment at one level, and in the presence of multilevel disease with similar findings at each level. Thus the requested procedure at L5/S1, per the note of 10/18/2005 is not warranted. On 12/01/2005 Dr. Wharton recommends a disc replacement at L4/5 and a fusion at L3/4 and L5/S1. This type of surgical construct violates the criteria for artificial disc replacement if it had been a proven procedure.

In this injured individual the clinical data and the imagining studies failed to substantiate the need for any invasive treatment. She has multilevel disease and this is not amenable to surgical treatment. In fact in reviewing the clinical data the injured individual complained of pain over the left lumbosacral region at the time of her first visit to Dr. Wharton. This finding did not substantiate the osteoplasty procedure performed on the injured individual since she continued to have the same complaints after the osteoplasty procedure.

The submitted letters of medical necessity and explanations about the charges for this procedure are not substantiated by objective scientific data that shows this procedure to be either necessary or effective in the long term in altering the natural history of chronic low back pain associated with aging of the lumbar spine. Furthermore the history of back and bilateral buttock pain is more suggestive of symptoms of spinal stenosis.

The following excerpts from an article by Hanley, E, in the Journal of Bone and Joint Surgery 2006 clearly raises concerns about the belief held by some that artificial disc replacement are an viable option in the management of chronic low back pain secondary to multilevel degenerative lumbar spondylosis.

“The available information on the diagnosis and treatment of low-back pain lacks objectivity, as most studies have been retrospective, uncontrolled, and predominantly focused on operative technique. Most investigators have used nonvalidated outcome measures that have reflected the biases of their proponents.”

“So-called facet disease and degenerative instability are extremely rare, and these diagnoses should seldom be used as indications for operative intervention. When they are present, stabilization with use of posterior instrumentation and arthrodesis is appropriate.”

“The pertinent issues revolve around the treatment of idiopathic and discogenic low-back pain. Major controversies center around which treatment is best when non-operative measures have failed. Opponents of operative treatment believe that the outcomes of most or all procedures fall below the threshold needed to justify operative intervention, as only about 50 percent of patients have a successful result with regard to decreased pain, increased function, and ability to return to work. Proponents of operative treatment maintain that these patients have no other options, that some improvement in pain and function is important, and that operative intervention is therefore warranted. They believe that full relief of disability is too strict a criterion or goal.”

“We think that most patients who have acute or chronic idiopathic or discogenic low-back pain should be managed non-operatively. Patients who have refractory pain with severe incapacity and those who have imaging-confirmed morphological changes and concordant symptoms may be managed successfully with anterior disc ablation and structural arthrodesis.”

“Some improvement occurs as a result of operative treatment in about 75 percent of patients, but major or complete relief of pain and recovery of function are seen in 50 percent or less. Each physician and each patient must assess these issues in a forthright manner and determine what is appropriate under the circumstances.”

Letters of medical necessity often state that “studies have clearly shown” that a lumbar fusion could “lead to altered biomechanical effects at adjacent segments, thereby leading to future and additional surgical requirements. By preservation of motion, similar to what has been noted in both total hip and total knee studies, and has now become commonsense experience, motion preservation by artificial replacement leads to greater outcomes with respect to pain relief and better function.” The comparison to total hip and knee replacements is inappropriate based on the marked differences in the normal range of motion (ROM) of these joints in comparison to the very limited ROM of the vertebral segments. Furthermore the claims of the so-called “cascade” effect and better outcomes because of preservation of “motion” in the lumbar spine remain unproven.

Regardless of the experimental and investigational status of the artificial disc device, this injured individual is not a candidate for any invasive treatment. A discogram study of one level has no clinical relevance since the purpose of the discogram is to determine the level of pain in comparison with a pain free level. In order to do this more than one level has to be tested. Furthermore the MRI study as reported in the office note {actual report not provided} revealed only minimal changes that could be related to aging of the lumbar spine. The changes on the MRI were not of sufficient magnitude to warrant the discogram study or even consider invasive treatment.

Surgeons writing letters in support of the artificial disc replacement will often make a statement that “it is well known and documented that artificial disc replacement can help decrease and minimize the potential for adjacent segment disease”. The literature search failed to reveal any scientific evidence to support this statement. In fact there is little literature documenting the so-called “cascade effect” of a one level fusion on adjacent segments. There is also no scientific data to show that the alleged degree of motion that would be preserved does in fact have any clinical relevance.

Aside from the fact that at the present time there is no scientific data to substantiate either the need for or the effectiveness of artificial disc replacement in altering the long-term outcomes of low back pain the clinical data fails to substantiate the need for any invasive treatment. The main concern about the FDA/IDE study is that the procedure was compared to an ALIF with BAK cages and bone graft that has not been shown to have a high success rate. The model selected for comparison was flawed with an inherent poor result. Thus the conclusion that the results of artificial disc replacement are superior to those after the ALIF/BAK/GRAFT procedure is not credible or valid. The ALIF/BAK is known to have an inferior end-result in comparison with ALIF/BMP-2 with or without posterior fixation. Therefore, any procedure compared with the ALIF/BAK/GRAFT would appear to have a better end result.

The FDA/IDE study suffers from all the pitfalls of any multicenter trial, in particular, when the majority of cases are from two centers. In fact the published papers do not clearly identify the number of patients from each center. Furthermore, a large percentage of patients continued to use narcotic pain medications two years after the artificial disc replacement that was supposed to alleviate their complaints of chronic low back pain. In addition five of the 5.4 percent of subjects

who required a second procedure had the disc replaced and ten had a fusion after removal of the implant. This is a high rate of complication in the initial phase of the study particularly when one considers that the surgeons performing this procedure were established spine surgeons and had been trained to perform this procedure. Replacing the disc is likely to be associated with an increased risk of morbidity particularly to the neurovascular structures in the vicinity of the vertebral bodies.

RECORDS REVIEWED:

Notification of IRO Assignment dated 03/15/06

MR-117 dated 03/15/06

MES-14 dated 09/11/03

DWC-60

DWC-69: Reports of Medical Evaluation dated 05/17/04, 10/08/03

DWC-73: Work Status Reports dated 05/12/03 through 03/13/06

Alternate DWC-62: Explanation of Benefits dated 04/06/04 (two), 04/07/04, 07/19/04, 07/21/04, 04/06/04, 02/10/05

MCMC: IRO Medical Dispute Resolution Prospective dated 03/20/06

MCMC: IRO Acknowledgment and Invoice Notification Letter dated 03/16/06

Mayfield Weedon: Letter dated 03/29/06 from Amy Gay, Legal Assistant

Forte: Letter dated 03/02/06 from Joel Wilk, M.D.

Forte: Notice of Utilization Review Findings dated 02/16/06, 01/26/06, 07/26/04, 04/05/04, 02/19/04

Ortho Rehab Associates: Fax Cover Page with handwritten note dated 02/16/06

Ortho Rehab: Letter dated 02/06/06 from George Wharton, M.D.

Forte: Letters dated 01/26/06, 07/26/04, 02/19/04

Metropolitan Radiology: Lumbar discogram, post-discogram lumbar CT dated 10/14/05

Metropolitan Radiology: Sedation Monitoring Form and Observation Monitoring Form dated 10/14/05

Forte: Authorization for Requested Services dated 10/03/05

Occupational Health Resources Intl': Report dated 09/12/05 from Larry Stetzner, M.D.

Churchill Evaluation Centers: Reports of Medical Evaluation dated 08/19/05, 01/31/05, 05/17/04 from John Steele, M.D. with attached Reviews of Medical History and Physical Examinations

Academy Rehab: Letters dated 06/29/05, 02/10/05 from Joe Huggins, D.C.

Interventional Pain Management: Letter dated 05/05/05 from Mark Hackbarth, M.D.

Tyler Neurosurgical Associates: letter dated 04/29/05 from Karen Mills, Workers' Compensation Liaison

CHS: Notice of Disputed Issue(s) and Refusal to Pay Benefits dated 04/25/05

Tyler Neurosurgical Associates: Authorization for Disclosure of Confidential Information dated 03/14/05

Working Rx: Letter dated 03/08/05 from Heather Patten

Working Rx: Invoice dated 01/28/05

Good Shepherd Medical Center: Instruction sheet dated 01/22/05

Envelope addressed to Joyce White postmarked 01/19/05 with note "Lady @ Good Shepherd"

IMO: Report dated 11/15/04 from Tricia Echols, Utilization Review Nurse

Handwritten note dated 10/06/04 from claimant
Spinal Rehabilitation Associates I: Prescription sheets dated 09/29/04 for Zoloft, Lortab, Provigil, Zanaflex
The Ortho Spine Clinic: Follow-Up Office Visit notes dated 08/26/04, 11/03/03
Forte: Notice of Intent to Issue an Adverse Determination dated 07/23/04
Mayfield Weedon, L.L.P.: Fax Transmission Sheet dated 05/13/04
G. Peter Foox, M.D.: Prescription notes dated 05/13/04, 01/15/04
Diagnosis Verification Inquiry dated 05/13/04
ETMC: Fax Cover Sheet with handwritten note dated 08/13/04
George Wharton, M.D.: Handwritten note dated 07/13/04
Blue Cross Blue Shield of Texas: Letter dated 04/29/04 from Maya Borski, Reimbursement/Subrogation Department
Ortho Rehab: Letter dated 04/16/04 from George Wharton, M.D.
Blue Cross Blue Shield of Texas: Letter dated 03/23/04 from Michael Chalcraft, Corporate Reimbursement/Subrogation
Ortho Rehab Associates: S.O.A.P. notes dated 03/23/04, 07/13/04, 11/04/04, 10/11/05, 10/18/05, 12/01/05 from George Wharton, M.D.
Healthsouth Medical Center: Operative Report dated 02/23/04 from George Wharton, M.D.
Ortho Rehab Associates: Roentgenographic Interpretation dated 02/10/04 from George Wharton, M.D.
Ortho Rehab Associates: Narrative Report dated 02/10/04 from George Wharton, M.D.
Lumbar myelogram and post myelogram CT lumbar spine dated 01/12/04
Richard G. Buch, M.D.: Report dated 12/31/03
Medical Records Release Form signed 12/31/03
Good Shepherd Medical Center: Bone density DXA dated 12/15/03
Tyler Open MRI & Diagnostic Imaging: Patient information sheet dated 11/20/03
Occupational Health Resources Intl': Required Medical Examination dated 11/18/03
DWC: Required Medical Examination Notice or Request for Order signed 11/10/03
CHS: Letters dated 11/07/03, 09/18/03 from Debbie Miller, Sr. Claims Representative
MRI lumbar spine dated 06/11/03
Tyler Open MRI: MRI lumbar spine (date not legible, year 2003)
CHS: Undated letter from Linda Madsen, Sr. Claims Representative
Good Shepherd Occupational Medicine Services: Undated letter from David Stanley, PA-C
Academy Rehab: Undated letter from Joe Huggins, D.C.
G. Peter Foox, M.D.: Undated facsimile transmittal with note stating claimant has appointment on 01/22
Handwritten note with claimant's name at top stating here for MRI on 01/12/04

The reviewing provider is a **Licensed/Boarded Orthopedic Surgeon** and certifies that no known conflict of interest exists between the reviewing Orthopedic Surgeon 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 prior to referral to the IRO. The reviewing physician is on DWC's Approved Doctor List.

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.

This decision is deemed received by you 5 (five) days after it was mailed (28Tex.Admin. Code 102.4(h)(2) or 102.5(d)). A request for a hearing **and a copy of this decision** should be sent to:

Chief Clerk of Proceedings / Appeals Clerk
Texas Department of Insurance Division of Workers' Compensation
P.O. Box 17787
Austin, Texas, 78744
Fax: 512-804-4011

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 commission 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

6th day of April 2006.

Signature of IRO Employee: _____

Printed Name of IRO Employee: Beth Cucchi