

MCMC

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

Date:	12/16/2005
Injured Employee:	
Address:	
MDR #:	M2-06-0191-01
DWC #:	
MCMC Certification #:	IRO 5294

REQUESTED SERVICES:

Please review the item(s) in dispute: Pre-authorization denied for L5-S1 Charite artificial disk replacement.

DECISION: Upheld

IRO MCMC llc (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 12/16/2005, concerning the medical necessity of the above referenced requested service, hereby finds the following:

The artificial disc is experimental and investigational.

CLINICAL HISTORY:

This 42-year-old male was allegedly injured on ___ in a motor vehicle accident (MVA) when his car was rear-ended. He had a prior history of another MVA on 08/29/2002 when he was rear-ended. He has not worked since December 2002. The MRI of 10/03/2002 revealed a diffused protruded disc at L5/S1 that extended into the left foramen with resultant stenosis of the lateral recess and foramen. There was also moderate facet arthropathy. There was also a 4cms size cyst near the right kidney. The EMG/NCV study of 05/15/2003 revealed mild to moderate left S1 radiculopathy.

Dr. Flemming [neurologist] evaluated the injured individual on 06/02/2003 for pain in his neck and low back. The back pain radiated to his left leg and down to his toes. He was said to have mechanical low back pain and was sent for a second EMG/NCV that essentially revealed irritation of the L5 and S1 innervated muscles bilaterally, left more than right. A myelogram/CT scan was recommended. The injured individual was given a series of lumbar epidural steroid injections.

The next noted is dated 06/08/2004 from Dr. Wright. The injured individual was told that surgery was not being recommended and another series of epidural steroid injections (ESI) were recommended. There is a note from a psychologist dated 08/16/2004 that recommends a multidisciplinary behavioral chronic pain management program. Dr. Wright also agreed with this recommendation. The note of 10/14/2004 only documents administrative issues about coverage and correspondence with DWC.

REFERENCES:

Disc Replacements: "This Time Will We Really cure Low-Back and Neck Pain", by Boden, S.D. et al. The Journal of Bone and Joint Surgery [American] 86:411-422 [2004].

Cinotti G, David T, Postacchini F. "Results of disc prosthesis after a minimum follow-up period of 2 years". Spine. 1996; 21 (8) 995-1000.

Guyer, R and Ohnmeiss, D. "Intervertebral Disc Prosthesis" Spine: Vol 28 # 155:20003. pp 515-523.

McAfee, P.C. et al: "SB Charite Disc Replacement", J of Spinal Disorders and Techniques. Vol.16: No. 4: pp 424-433, 2003.

RATIONALE:

Dr. Sloan who appears to work with Dr. Wright evaluated the injured individual on 12/21/2004 for increasing low back and left leg pain. He claimed to have actually lost bladder control several times but had no ongoing symptoms. He was said to have positive straight leg raise (SLR) test on the left and some weakness of his quads, hamstrings, tibialis anterior, extensor hallucis longus (EHL) and calf muscle. He allegedly had changes in the sensation from the thigh to the posterolateral aspect of the leg and dorsum of the foot where he allegedly had no sensation.

The MRI of 01/03/2005 revealed a previous left hemilaminectomy defect at L5/S1 with a disc protrusion and scar tissue producing relative stenosis of the left lateral recess and foramen. The right renal cyst was still present. On 01/06/2005 he complained of pain in the right flank. The note however does not document whether the injured individual was evaluated for any kidney problem. On 02/21/2005 Dr. Wright [orthopedic] referred him to Dr. Vivek Khushwaha.

Dr. Khushwaha [orthopedic] evaluated him on 03/03/2005 and found decreased range of motion (ROM) of his low back associated with pain and a positive SLR test on the left. It is not clear why he recommended facet joint injection. These were however denied. On 08/02/2005 he complained of severe back and leg pain that was worse in his back. The x-rays did not show any evidence of significant facet disease. The disc height was said to be well maintained and Dr. Khushwaha recommended artificial disc replacement.

The clinical data suggest that the injured individual's symptoms are not commensurate with the imaging findings. Furthermore the imaging findings had revealed moderate changes of degenerative lumbar spondylosis. The injured individual's level of pain is not commensurate

with the imaging findings. Given the complaint of leg pain prior to surgery, recurrent disc protrusion as well as the non-anatomical findings that were not commensurate with the imaging studies, the proposed surgery is inappropriate and not warranted.

Standard therapy for lumbar disc disease involves a period of conservative treatment, consisting of physical therapy (PT) and reduced activity, followed by gradually increasing mobilization and exercise. Surgical treatment is undertaken only for those injured individuals who have not improved with conservative treatment or who have a severe neurological impairment such as cauda equine syndrome. Although minimally invasive procedures such as microdiscectomy and laparoscopic discectomy are available, approximately 200,000 disc excision surgeries are performed in the United States each year and the standard approach has been the open laminectomy with discectomy in which portions of the vertebra and disc are removed. Injured individuals may also undergo fusion of the vertebrae adjacent to the affected disc using bone grafting. However problems may arise after spinal fusion, including non-union and loss of spinal curvature and flexibility.

In an attempt to avoid problems associated with spinal fusion, a new technique has been developed in which the diseased spinal disc is surgically removed and replaced with an artificial disc. The goal of this procedure is to reduce or eliminate back pain while maintaining spinal curvature, flexibility and load bearing. There are several artificial disc devices in various stages of clinical developments. One such disc is the SB Charite III (Waldemar Linck GmbH and Co., Hamburg, Germany). This device is composed of two cobalt-chromium endplates that are attached to the vertebrae and a polyethylene disc that is inserted between the metal endplates. Prostheses for artificial total lumbar disc replacement are regulated by the FDA as Class III devices that are subject to the most extensive regulations enforced by the agency. Currently, only one such device has been approved for marketing in the United States to be used in one level only.

The recently concluded two-year FDA approved study of the Charite disc has been analyzed and the data submitted to the journal *SPINE* for publication this year. In verbal discussions with the investigators of the study the early results suggest that initially the degree of pain relief is greater after the disc replacement. These injured individuals are also more mobile and recover from the effects of surgery at a more rapid rate and also tend to return to functional activities much sooner. However, at the end of two years the differences are less marked between the two groups. It should be remembered that the artificial disc replacement is being compared with a fusion as if it were the gold standard for the treatment of chronic low back pain.

A recent article by Boden et al attempts to answer this question about the usefulness of the disc replacement procedure.

The authors concluded that:

"The description of intervertebral disc replacement is eerily similar to that of lumbar arthrodesis but with an odd twist. Arthrodesis is currently held up as the "gold standard" against which disc replacement is compared. In no way can arthrodesis be considered a gold standard. At best, the mediocre results of spinal arthrodesis for the treatment of back pain should be considered a weak

comparison. Attempting to make the case that the results of disc replacement are similar to those reported for spinal arthrodesis to justify marketing and implantation of these devices is suspect. A review of the extensive literature on spinal arthrodesis for the treatment of back pain indicated that "some improvement occurs as a result of operative treatment in about 75% of injured individuals, but major or complete relief of pain and recovery of function are seen in 50% or less." Early series of disc replacements appear to have had similar success rates.

We know of no satisfactory scientific literature on disc replacement in the cervical spine. In the meager literature on disc replacement in the lumbar spine, success rates of approximately 70% with poorly defined outcome criteria have been reported. Perhaps, if the outcome criteria are more appropriately defined, the success rates will be substantially lower. Published reoperation rates have ranged from 5% to >20% with complications reported in >10% of the injured individuals.

RECORDS REVIEWED:

- Notification of IRO Assignment dated 10/25/05
- MR-117 dated 10/25/05
- DWC-60
- DWC-73: Work Status Reports dated 08/02/05, 05/05/05 and two undated
- MCMC: IRO Medical Dispute Resolution Prospective dated 11/22/05
- MCMC: IRO Medical Dispute Resolution M2 Prospective Pre-Authorization dated 10/27/05
- The Hartford: Review Determination reports dated 09/21/05, 08/25/05, 04/04/05, 10/15/04, 09/01/04, 06/15/04
- Orthopedic Associates: Office notes dated 08/02/05, 05/05/05, 03/03/05 from Vivek Kushwaha, M.D.
- Envoy Medical Systems: Notice of Independent Review Decision dated 07/07/05 from Daniel Chin
- W/Comp Precertification Requests dated 06/08/05, 04/04/05
- Memorial Hermann Hospital: Physician's Orders dated 06/08/05, 04/04/05
- ___: Letter dated 04/11/05
- UniMed Direct: Physician Advisor Referral Form dated 04/01/05
- B. T. Wright, Jr., M.D.: Letter dated 02/21/05
- B. T. Wright, Jr., M.D.: Office notes dated 01/06/05, 10/14/04, 09/14/04, 06/08/04
- North Houston Imaging Center: MRIs lumbar spine dated 01/03/05, 10/03/02
- Sonja Sloan, M.D.: Office note dated 12/21/04
- Christus St. Joseph Hospital: Handwritten form note signed 12/21/04
- Metropolitan Orthopedic Associates: Prescription note from B. T. Wright, Jr., M.D. dated 12/21/04 and one undated
- Pain & Rehabilitation Solutions: Psychodiagnostic Examination report dated 08/16/04 from Blanche Khan, M.A.
- Cigna Healthcare Coverage Position, "Invasive Treatment of Back Pain", effective 08/15/04
- River Oaks Imaging and Diagnostic: Lumbar epidural steroid injection dated 11/04/03

- River Oaks Imaging and Diagnostic: Epidural steroid injection via right S1 nerve root dural sleeve dated 10/28/03
- DWC: Certificate of Registration Approved Doctor List dated 08/27/03
- Shelly Finch-Fowinkle: Letter dated 08/23/04
- River Oaks Imaging and Diagnostic: Epidural Steroid Injection report dated 07/07/03
- Memorial Neurological Association: Electromyogram and Nerve Conduction Studies Report dated 06/27/03
- Memorial Neurological Associates: Neurological Evaluation follow-up note dated 06/27/03 from William Fleming, III, M.D.
- Memorial Neurological Associates: Neurological Evaluation dated 06/02/03 from William Fleming, III, M.D.
- Texas Electrophysiology Services: EMG/nerve study dated 05/15/03
- DWC: Undated Order for Payment of Independent Review Organization Fee
- DWC: Undated Notice of Medical Payment Dispute
- Metropolitan Orthopedic Associates: Undated Patient Referral form with handwritten notes
- Workers Comp – Patient Profile (undated)
- North American Spine Society: Article entitled, “Lumbar Zygapophyseal (Facet) Joint Injections” (undated)
- BlueCross BlueShield of Tennessee Medical Policy Manual, “Lumbar Facet Steroid Injections for Treatment of Low Back Pain”, pages 1 and 2
- National Library of Medicine: Article entitled, “Lumbar zygapophyseal joint injections in patients with chronic lower back pain”, pages 1 and 2

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

16th day of December 2005.

Signature of IRO Employee: _____

Printed Name of IRO Employee: _____