

MCMC

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

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|------------------------------|----------------------|
| Date: | 4/8/05 |
| Injured Employee: | |
| Address: | |
| | |
| MDR #: | M2-05-1121-01 |
| TWCC #: | |
| MCMC Certification #: | 5294 |

REQUESTED SERVICES:

Review the item in dispute to address the prospective medical necessity of the proposed Bio 1000 system, regarding the above-mentioned injured worker.

DECISION: UPHELD

MCMC llc (MCMC) is an Independent Review Organization (IRO) that has been selected by The Texas Workers' Compensation Commission (TWCC) to render a recommendation regarding the medical necessity of the above requested service.

Please be advised that a MCMC Physician Advisor has determined that your request for an M2 Prospective Medical Dispute Resolution on 3/15/05, concerning the medical necessity of the above referenced requested service, hereby finds the following:

The purchase of a Bio 1000 system is not medically necessary. The Bio 1000 is investigational and unproven.

CLINICAL HISTORY:

The injured individual is a 45-year-old morbidly obese male with a date of injury (DOI) of _____. He weighs over 300 lbs. He had a knee scope in May of 2003 and two in 2001, prior to this injury. He has had multiple injections from 2003 to 2005, in addition to a cane and a knee immobilizer. Her takes bextra and glucosamine. The diagnosis is degenerative joint disease (DJD) and chondromalacia of the left knee. The Bio 1000 system is recommended. Not only is this unit clinically unproven according to the literature, but there is no way to link his diagnosis directly to the DOI, as the chronic findings and two prior surgical interventions do not support any direct relationship. Also, the injured individual's morbid obesity is undoubtedly impacting on his past and current knee pain and that has yet to be addressed.

RATIONALE:

The Bio 1000 system is FDA approved for usage as a form of electrical stimulation in osteoarthritis of the knee. However, this does not mean it is a proven treatment, only

that it is theoretically not harmful to the user. The literature indicates it hypothetically may help, but is unproven and not efficacious. Reference #1 was done on in-vitro cells but the results have not been reproduced in vivo. The other references indicate there is a lack of clinical data, long term studies, and controlled trials to support this type of treatment.

REFERENCES:

1. Clin Ortho and Rel Res Oct 2004;S163-172 Wang W.
2. Cochrane Database Syst Rev 2002(1):CD003523 Hulme J.
3. Cochrane Database Syst Rev 2001(3):CD003222 Carroll D.
4. ACOEM guidelines copyright 2004 pg 300.

RECORDS REVIEWED:

- TWCC Notification of IRO Assignment dated 3/15/05
- TWCC MR-117 dated 3/14/05
- TWCC-60
- TWCC-1 dated 1/21/03
- TWCC-69 dated 9/9/03, 2/18/04
- Unimed Direct, LLC: Adverse Determination letter dated 1/28/05, 2/10/05
- Arkansas Claims Management, Inc: Letter from Raina Robinson dated 3/21/05; Independent Review Organization Summary dated 3/18/05
- Titus Regional Medical Center: Emergency Room record dated 1/21/03; Xray report left knee dated 1/21/03; Emergency Room record dated 3/27/02; Left Lower Extremity Venous Doppler and Ultrasound report dated 3/27/02
- Bruce R. Beavers, MD: Confirmatory Consultation dated 4/28/03; Required Medical Examination dated 10/24/02
- Ambulatory Surgery Center of Tyler: Operative Report for DOS 5/8/03; Anesthesia record dated 5/8/03; Operative Report for DOS 1/4/02
- Azalea Orthopedic and Sports Medicine Clinic: Initial Evaluation and Plan of Care dated 6/18/03; Office Notes dated 11/13/01 to 1/7/05; MMI and Impairment Rating dated 2/18/04; Radiographic Interpretation of L Knee dated 2/18/04; MMI and Impairment Rating dated 1/8/03; Letter of Medical Necessity dated 11/4/04
- Couch Physical Therapy and Rehabilitation Center: Notes dated 7/23/03
- East Texas Medical Center: Xray L Tibia-Fibula report dated 8/20/01 and Left Knee dated 8/20/01; History and Physical dated 10/1/01; Xray of Chest done 10/1/01; Hospital Records for admission of 10/1/01; Surgical Record dated 10/4/01; Physical Therapy Initial Evaluation dated 3/12/02; Physical Therapy Discharge Summary dated 4/1/02; Notes for DOS 3/12/02 to 3/29/02
- Open Imaging of Mt. Pleasant: MRI of L Knee done 8/21/01; MRI of L Calf done 8/21/01
- Cyprus Orthopaedic Group, PA: Office Note 11/7/01
- Robert Winans, MD: Designated Doctor Exam dated 4/3/02

- Texas Spine and Joint Hospital: MRI L Knee report dated 2/7/03
- Bionicare: Letter of Medical Necessity dated 1/7/05

The reviewing provider is a Boarded Anesthesiologist and certifies that no known conflict of interest exists between the reviewing Anesthesiologist and any of the treating providers or any providers who reviewed the case for determination prior to referral to the IRO.

Your Right to Request A Hearing

Either party to this medical dispute may disagree with all or part of the decision and has a right to request a hearing.

If disputing a spinal surgery prospective decision a request for a hearing must be in writing and it must be received by the TWCC Chief Clerk of Proceedings within 10 (ten) days or your receipt of this decision (28Tex.Admin. Code 142.5©.)

If disputing other prospective medical necessity (preauthorization) decisions a request for a hearing must be in writing and it must be received by the TWCC Chief Clerk of Proceedings within **20** (twenty) days of your receipt of this decision (28Tex.Admin. Code 148.3©.)

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 Workers' Compensation commission
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

8th day of April 2005.

Signature of IRO Employee: _____

Printed Name of IRO Employee: _____