

MCMC

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

Date:	5/25/05
Injured Employee:	
Address:	
MDR #:	M2-05-1273-01
TWCC #:	
MCMC Certification #:	5294

REQUESTED SERVICES:

Review the item in dispute, regarding the medical necessity of the Bio-100 System.

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 4/15/05, concerning the medical necessity of the above referenced requested service, hereby finds the following:

The Bio-1000 system is not medically necessary.

CLINICAL HISTORY:

The injured individual is a 53-year-old female with a date of injury (DOI) of ____, with resultant right knee pain. She had right knee arthroscopy in 2001 for another work related injury, but has not had one for this injury. She is also morbidly obese at 4'11" and 217 lbs. Physiotherapy, Cox 2 inhibitors, and five hyalgan injections have not helped her, and her surgeon recommended the Bio 1000 unit to be used at home for her knee. According to the Attending Physician (AP), her X-rays show lateral joint space narrowing with degenerative changes. Two Independent Medical Examiners agreed with the diagnosis of work-related post-traumatic knee arthritis and felt a Total Knee Replacement would be needed in the future. She was sent back to work with restrictions in 09/2004, but she was subsequently laid off and claims that her knee continues to bother her. The measured range of motion of the right knee has actually decreased during her treatment with her AP. The literature continues to study the Bio-1000 system and similar pulsed electrical stimulation systems as regards chondrocyte proliferation. However, this type of treatment remains unproven.

RATIONALE:

While the Bio 1000 may be FDA approved for usage as a form of electrical stimulation in osteoarthritis of the knee, this does not mean it is a proven treatment. The literature indicates that hypothetically it may help, but it remains unproven as far as efficacy. Ref #1 was done on in vitro cells in a lab but the results have not been reproduced in vivo. The other references indicate there is a lack of long term studies, clinical data, and controlled trials to support this type of treatment. The references supplied with this case are faulty, as the first reference is as yet unpublished, is unblinded, non-randomized, and without placebo control. The second reference states: "Studies for long term effects are warranted" as this study only encompassed a four week period.

REFERENCES:

1. Clin Ortho and Res Res 2004 Oct;S163-72 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 '04 pg 300.
5. Cochrane Database Syst Rev 2003 (1):Osiri M.

Literature accompanying this case includes two papers: one is an unpublished presentation from 03/2004 by Mont MA. The other is J Rheumatol 1995;22:1757-61 Zizic TM.

RECORDS REVIEWED:

- TWCC Notification of IRO Assignment
- TWCC MR-117
- TWCC-60
- Concentra: Denial letters dated 2/15/05, 2/28/05
- Bionicare booklet, letters, product information and articles

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

25th day of May 2005.

Signature of IRO Employee: _____

Printed Name of IRO Employee: _____