

MCMC

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

Date:	4/26/05
Injured Employee:	
Address:	
MDR #:	M2-05-1004-01
TWCC #:	
MCMC Certification #:	5294

REQUESTED SERVICES:

Please review the service in dispute regarding the purchase of a Bio-1000 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 2/24/05, concerning the medical necessity of the above referenced requested service, hereby finds the following:

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

CLINICAL HISTORY:

The injured individual is a 41-year-old female with date of injury of _____. The diagnosis is degenerative joint disease of the right knee. An MRI of 01/1999 showed early degenerative arthritis. The injured individual cannot take NSAIDs per the Attending Physician's (AP) note. His report of 07/2004 states the knee Xray looks good and doesn't show much arthritis at all. The individual is status post surgery, PT, synvisc, and cortisone injections. Not only is there limited Xray evidence to support severe osteoarthritis of the knee, but the Bio-1000 system is not proven according to the literature.

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 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.

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.

RECORDS REVIEWED:

- TWCC Notification of IRO Assignment dated 2/24/05
- TWCC MR-117 dated 2/24/05
- TWCC-60
- Health Direct, Inc.: Utilization Review Determination dated 1/14/05
- Bionicare: Letter of Necessity dated 1/20/05; Bio-1000 Prescription; Product Information and articles;
- Flahive, Ogden and Latson: Response letter dated 3/7/05; Summary of Carrier's Position dated 2/17/05; Carrier's Exhibits; Cigna Healthcare Coverage Position
- HealthSouth: Report of MRI left knee dated 1/19/99
- Azaler Orthopedic & Sports Medicine Clinic: Office Notes 1/20/04 to 12/28/04
- James R. Harris, MD: Letter of medical necessity dated 1/19/05

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

26th day of April 2005.

Signature of IRO Employee: _____

Printed Name of IRO Employee: _____