

MCMC

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

Date.....3/1/05
Injured Employee.....
MDR #.....M2-05-0765-01
TWCC#.....
MCMC Certification #..5294

DETERMINATION: Denied

Requested Services:

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

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 2/3/05, concerning the medical necessity of the above referenced requested service, hereby finds the following:

The proposed Bio-1000 system is medically unnecessary as it is investigational and unproven.

This decision is based on:

- TWCC Notification of IRO Assignment dated 2/3/05
- TWCC MR-117 dated 1/31/05
- TWCC-60 stamped received 1/18/05
- Concentra: Reviews dated 1/12/05, 1/04/05
- Texas Outpatient Non-Authorization Recommendation dated 12/2/04
- Genex: Texas Outpatient Non-authorization dated 12/2/04
- Flahive, Ogden & Latson: Summary of Carrier's Position dated 1/28/05
- Cigna Healthcare Coverage Position (Effective Date 12/15/04) Subject: Bionicare Bio System
- Palmetto Government Benefits Administrators Coverage and Payment rules for TENS.0403
- Bio-1000 brochure and product information
- Bionicare: Appeal reply letter dated 1/5/05; Prescription & letter of Medical Necessity dated 4/22/04; list of References
- McConnell Orthopedic Clinic, PA: Prescription for DME dated 4/22/04; History and Physical dated 3/5/04
- David Bradley, BS: Reports dated 4/9/04, 5/7/04, 6/18/04, 8/20/04
- Article: "Up-Regulation of Chondroctye Matrix Genes and Products by Electric Fields by Wei Wang, MD, et. al

The injured individual is a 60-year-old female with date of injury of _____. The injured individual had an MRI a few days after injury which showed "severe tricompartmental degenerative arthrosis, chondromalacia, and probable ACL tear". It is not possible that the acute injury caused any of the severe degenerative changes in such a short time. The injured individual has had PT, knee injections, and now the Bio 1000 system is recommended. Not only is this unit clinically unproven according to the literature, but her diagnosis cannot be linked to the date of injury as the chronic findings on MRI do not support any direct relationship.

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. The literature indicates that 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.

This decision by MCMC is deemed to be a Commission decision and order (133.308(p) (5)).

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

1 day of March 2005.

Signature of IRO Employee: _____

Printed Name of IRO Employee: _____