

# MCMC

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

<b>Date:</b>	<b>02/08/2006</b>
<b>Injured Employee:</b>	
<b>Address:</b>	
<b>MDR #:</b>	<b>M2-06-0573-01</b>
<b>DWC #:</b>	
<b>MCMC Certification #:</b>	<b>IRO 5294</b>

### REQUESTED SERVICES:

Please review the item(s) in dispute: Pre-authorization denied for rental of Bio 1000 for four months.

### DECISION: Upheld

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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 12/08/2006, concerning the medical necessity of the above referenced requested service, hereby finds the following:

Uphold denial for rental of the BIO-1000 unit for four months.

### CLINICAL HISTORY:

This 54-year-old female was allegedly injured on \_\_\_\_\_. She has apparently been treated for symptoms related to her knee. She was given medications, physical therapy (PT), assistive devices, intra-articular steroid and Hyalgan injections for more than three months.

### REFERENCE:

Zizec et al. The Treatment of Osteoarthritis of the Knee with Pulsed Electrical Stimulation. J Rheumatol 1995;22:1757-61.

### RATIONALE:

The only clinical information consists of preprinted lists of criteria that are checked off. The injured individual allegedly has limitation of all activities of daily living (ADL) secondary to pain. The following signs and symptoms listed in the form are checked off: limp, loss of motion, mechanical symptoms, joint effusion, pain when using stairs, crepitation, positive Apley test, imaging findings of synovial effusion.

There is a letter of medical necessity that the durable medical equipment (DME) requested can “not only reduce symptoms but also reduce the need for narcotic pain medication and NSAIDS/Cox-2 inhibitors”. In addition this DME would allegedly “also postpone the need for more extensive reconstructive surgery such as a total knee arthroplasty (in some cases for many years).

The initial study presented to the FDA for a PMA certificate was based on the results in 32 patients who used the active device in contrast to the findings in 21 patients who used the inactive device. Thus the study was performed on 53 patients only, and not on the 78 patients enrolled in the study. The 53 patients wore the unit for at least six to ten hours a day. The data was summarized in four graphs. The vertical axis lists “Improvement on a Visual Analog Scale” in increments of 0.4 starting at 0.0 and ending at 2.4. This short spread on the VAS that is depicted along the entire vertical axis that extends over a vertical height of three inches gives an erroneous impression of the accuracy, credibility and validity of the data.

In each graph the “n” value for those who used the active device varies. The graphs related to “intent to treat” list 41 patients with the active unit and 37 with the inactive unit. The two graphs related to “Time compliant Completers” lists 32 active units and 21 inactive units. Thus only 53 patients used the assigned unit for six to ten hours. The graphs appear to show a great difference because of the manner in which the data was plotted on the vertical and horizontal axis.

Essentially this presentation to the FDA only provides data that suggests the possibility of some benefit with this unit and that the unit does not violate the patient and is therefore safe. However, there is no documented power study that will define the number of patients that would need to be treated to determine the efficacy of this unit.

The manufacturer cites a 10-year study, begun in 1993, that apparently showed that total knee replacement (TKR) can be avoided, for at least ten years, with the use of the BIO-1000 System. There are no details of the methods used to eliminate bias and confounding factors. The information submitted for review consists of a Rheumatology newsletter, a basic science study on the regulation of chondrocyte matrix genes and products by electric fields, and a study on rabbits. There were 37 rabbits divided into five groups leaving a very small number in each group. The data from this experiment can only be considered to be preliminary data to substantiate further studies. The results cannot be construed as evidence that the BIO-1000 System is effective in preventing progression of osteoarthritis and avoidance of a TKR.

The study touted as positive evidence of the effectiveness of the B10-1000 system in avoiding a TKR for as long as ten years, was reported at the AAOS annual meeting in 1999. There were 167 patients from 23 centers giving an average of seven patients per center. This number is very small and insufficient to draw any meaningful conclusions. The fact that 23 centers were involved compounds the errors related to bias and increases the confounding factors. The collection and interpretation of data in such a patient population immediately raises questions about bias and accuracy of reporting the results. Any statistical calculations from the data tabulated in this manner would lack credibility, reliability and validity. Thus this report cannot be

considered to be a scientific study and the numbers reported should not be discussed as "scientific data".

The Framingham Heart Study has clearly shown that overweight individuals are prone to develop osteoarthritis of the knees at an early age. Losing 10 to 20 percent of the excess weight did in fact avoid the need for a TKR for at least five years. There was a positive correlation between weight loss and need for a TKR. The more weight that was lost the longer the TKR could be postponed. This is proven to be true in the Framingham Heart Study.

Therefore, based on the available published data and promotional material from the manufacturer, this DME has not been shown to be either necessary or effective in altering the long-term outcomes of osteoarthritis of the knee. The cobbling together of isolated scientific facts and hypothesis into a pastiche to substantiate the effectiveness of this DME does not constitute scientific evidence. Regardless the data that was sent in support of the need for this DME is not valid, credible or reliable. Therefore, this DME is not warranted.

**RECORDS REVIEWED:**

- Notification of IRO Assignment dated 01/13/06
- MR-117 dated 01/13/06
- MR-100 dated 01/02/06
- DWC-60
- MCMC: IRO Acknowledgment and Invoice Notification Letter dated 01/17/06
- MCMC: IRO Medical Dispute Resolution Prospective dated 01/19/06
- Utilization: Letters dated 01/16/06, 01/09/06 from Carolyn Guard, RNC, Quality Assurance Consultant
- Bionicare: Letter dated 11/14/05 from Mary J Cronin, RN, Clinical Appeals Specialist
- Intracorp: Letters dated 10/30/05, 11/22/05 from Intracorp Medical Department
- Other Notification Confirmation dated 10/26/05
- Liberty Mutual: Fax note dated 10/26/05 from Arlene Jones
- Bionicare: Patient Knee Assessment dated 10/21/05
- Bionicare: Patient Information sheet dated 10/21/05
- Undated Statement of Medical Necessity/Letter of Medical Necessity
- Undated Prescription for Durable Medical Equipment (DME)
- The Magazine of Body Movement and Medicine: Volume XII Number 5/May 2005, cover and article entitled, "Electrical stimulation helps delay knee replacement surgery"
- Bionicare: Article entitled, "First & Only Non-drug, Non-invasive Treatment for Osteoarthritis of the Knee"
- Article entitled, "The use of Pulsed Electrical Stimulation (PES) to Defer Total Knee Arthroplasty (TKA) in Patients with Osteoarthritis (OA) of the Knee"
- Article entitled, "The Treatment of Osteoarthritis of the Knee with Pulsed Electrical Stimulation"
- Bionicare: Article entitled, "BioniCare Medical Technologies, Inc. BIO-1000 System"

- Article entitled, “Differentiation Between The BioniCare BIO-1000 System, Bone Stimulators and TENS”
- Article entitled, “Comparison of Currently Available Osteoarthritis Therapies”
- Article entitled, “The Bionicare BIO-1000 System”
- Article entitled, “Instruction for Use of the BIO-1000 System”

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**

**8<sup>th</sup> day of February 2006.**

**Signature of IRO Employee:** \_\_\_\_\_

**Printed Name of IRO Employee:** \_\_\_\_\_