

MEDICAL REVIEW OF TEXAS

[IRO #5259]

3402 Vanshire Drive

Austin, Texas 78738

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NOTICE OF INDEPENDENT REVIEW DETERMINATION

TWCC Case Number:	
MDR Tracking Number:	M2-05-0676-01
Name of Patient:	
Name of URA/Payer:	Insurance Co. of North America
Name of Provider: (ER, Hospital, or Other Facility)	Bionicare Medical Technologies
Name of Physician: (Treating or Requesting)	John McConnell, MD

February 7, 2005

An independent review of the above-referenced case has been completed by a medical physician board certified in physical medicine and rehabilitation. The appropriateness of setting and medical necessity of proposed or rendered services is determined by the application of medical screening criteria published by Texas Medical Foundation, or by the application of medical screening criteria and protocols formally established by practicing physicians. All available clinical information, the medical necessity guidelines and the special circumstances of said case was considered in making the determination.

The independent review determination and reasons for the determination, including the clinical basis for the determination, is as follows:

See Attached Physician Determination

Medical Review of Texas (MRT) hereby certifies that the reviewing physician is on Texas Workers' Compensation Commission Approved Doctor List (ADL). Additionally, said physician has certified that no known conflicts of interest exist between him and any of the treating physicians or providers or any of the physicians or providers who reviewed the case for determination prior to referral to MRT.

Sincerely,

Michael S. Lifshen, MD
Medical Director

cc: Bionicare Medical Technologies
John McConnell, MD
Texas Workers Compensation Commission

CLINICAL HISTORY

This is a lady who sustained a meniscal injury in _____. This was addressed with an arthroscopy and partial menisectomy. Maximum medical improvement was declared and an impairment rating was assigned. There is a gap in care for about four years. Recurrent knee pain was noted bilaterally and each knee was treated. There was a significant amount of degenerative change noted. Several different palliative procedures were attempted. Care waxed and waned over the next several years. Last year the symptoms increased and now there is a request for an investigative device designed to offer pain control and stave off the inevitable total knee replacement.

REQUESTED SERVICE(S)

Purchase of a Bionicare Bio-1000 System.

DECISION

Denied.

RATIONALE/BASIS FOR DECISION

The device requested is an experimental one that reportedly delivers a "proprietary electric" charge to the osteoarthritis and without the use of medications staves off the need for total knee replacement for up to four years. In the article presented to the AAOS at their most recent meeting, TKR can be delayed for up to four years. Aside from the manufacturers presentation at the AAOS, there is one article noted that suggests that there might be some efficacy and a Cochrane Review article noting a marked improvement in the placebo group as well as the tested group. There is an indication, but there is no clear controlled objective medical evidence of any real efficacy. Several national databases were consulted and electric stimulation is indicated in the acute phase but there is no discussion of an indication 13 years after the date of injury.

Further, there is a very limited amount of studies concerning the actual true efficacy of the device. An internet search only noted those articles supported by the manufacturer of the device and the two noted above. To my reading, there has not been any double blinded, peer-reviewed journal assessment of the efficacy of this device. A review of the vendor's literature cites an improvement of 120%. That point escapes me as a 100% improvement would be the abolishment of all pain complaints. How could it be better than complete resolution?

The injury sustained was a torn meniscus more than 10 years ago. Now this lady is developing an ordinary disease of life, an osteoarthritis and this is quite problematic. There is insufficient clinical evidence presented to support the use of this device in other than a controlled study scenario.

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) calendar days of your receipt of this decision (20 Tex. 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) calendar days of your receipt of this decision (28 Tex. Admin. Code 148.3).

This decision is deemed received by you 5 (five) days after it was mailed or the date of fax (28 Tex. Admin. Code 102.4(h) or 102.5(d)). A request for a hearing and a **copy of this decision** must be sent to:

Chief Clerk of Proceedings/Appeals Clerk
Texas Workers' Compensation Commission
P.O. Box 17787
Austin, Texas 78744

Or fax the request to (512) 804-4011. A copy of this decision must be attached to the request.

The party appealing the decision shall deliver a copy of its written request for a hearing to the opposing party 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 February, 2005.

Signature of IRO Employee: _____

Printed Name of IRO Employee: Cindy Mitchell