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NOTICE OF INDEPENDENT REVIEW DECISION

Date: March 7, 2005

Requester/ Respondent Address:

TWCC
Attention: Gail Anderson
7551 Metro Center Drive, Suite 100, MS-48
Austin, TX 78744-1609

Bionicare Medical Technologies
Attn: Kim Safka
Fax: 888-900-7354
Phone: 888-999-2361

Liberty Mutual Fire Insurance Co
Attn: Toni Evans
Fax: 864-576-4473
Phone: 800-664-CARE

RE: Injured Worker:

MDR Tracking #: M2-05-0948-01

IRO Certificate #: 5242

Forté has been certified by the Texas Department of Insurance (TDI) as an independent review organization (IRO). The Texas Workers' Compensation Commission (TWCC) has assigned the above referenced case to Forté for independent review in accordance with TWCC Rule §133.308 which allows for medical dispute resolution by an IRO.

Forté has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, relevant medical records, any documents utilized by the parties referenced above in making the adverse determination, and any documentation and written information submitted in support of the appeal was reviewed.

The independent review was performed by a orthopedic surgery reviewer (who is board certified in orthopedic surgery) who has an ADL certification. The physician reviewer has signed a certification statement stating that no known conflicts of interest exist between him or her and any of the treating physicians or providers or any of the physicians or providers who reviewed the case for a determination prior to the referral to for independent review. In addition, the reviewer has certified that the review was performed without bias for or against any party to this case.

Submitted by Requester:

- Notes from James R. Harris MD
- Appeal from Kim Safka
- MRI report 2-13-04

Submitted by Respondent:

- Document rejecting medical necessity of Bio-1000
- Appeal letter from Kim Safka
- Notes from James Harris MD
- MRI report 2-13-04

Clinical History

This is a 46 year old female who had an on-the-job knee injury on _____. She subsequently had two surgeries, the first was an anterior cruciate ligament reconstruction, and the second was a medial femoral chondroplasty and partial lateral meniscectomy by James Harris, MD. It was noted at the second surgery that she had an arthritic knee.

Requested Service(s)

Proposed BIO-1000 system for treatment of pain and symptoms associated with osteoarthritis.

Decision

I disagree with the insurance carrier and find the above device medically necessary.

Rationale/Basis for Decision

The Bionicare device was approved by the FDA for use as an adjunctive treatment for osteoarthritis in 2003. The research that led to the development of this device began in the 1960's and was pioneered by Carl Brighton, MD who subsequently was Chairman of the Department of Orthopaedic Surgery at the University of Pennsylvania and is now professor emeritus. His initial work was in studying piezo-electric fields and their relation to bone healing. This led to the modern day bone stimulators that are used in non- and delayed union of fractures. It was also found that there was a use for pulsed electrical stimulation in preventing cartilage breakdown. The original studies were done on rabbit cartilage and bovine chondrocytes. Subsequent human studies both in the US and Europe, have demonstrate that this is effective as adjunct treatment along with non-steroidal anti-inflammatory drugs and Visco supplementation in the treatment of arthritis. The indications are for use in mild to moderate arthritis in a stable well-aligned knee. _____ is only 46 years old and all means should be pursued to preserve her knee with non-operative treatment.

Reference:

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

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 (28 Tex. Admin. Code 142.5(c)).

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 142.5(c)).

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

Chief Clerk of Proceedings / Appeals Clerk
P.O. Box 17787
Austin, Texas 78744

Fax: 512-804-4011

The party appealing this decision shall deliver a copy of its written request for a hearing to other party involved in this 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 patient, the requestor, the insurance carrier, and TWCC via facsimile or U.S. Postal Service from the office of the IRO on this 7th day of March 2005.

Signature of IRO Employee:

Printed Name of IRO Employee: Denise Schroeder