

# IRO Express Inc.

An Independent Review Organization

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## IRO REVIEWER REPORT TEMPLATE -WC

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**DATE OF REVIEW:** 10/24/07

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

*DME Bio Knee device*

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION**

*Board Certified in Family Practice and has a Certificate of added qualification in Sports Medicine*

**REVIEW OUTCOME**

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

*Prior utilization review denials and rationales 9/7/07 and 9/17/07  
Medical records PAC, Dr. on 11/21/05, and Dr. dated 6/25/07, 7/23/07, 8/21/07  
Letter of medical necessity from Dr. on 7/2/07  
Summary about the Bionare Knee device- Medical, 2 pages  
ODG Guidelines*

**PATIENT CLINICAL HISTORY [SUMMARY]:**

Patient was originally seen for a Work Comp injury. He reported that a chair had moved under him and he landed on the floor. At the initial visit he complained of

low back pain and right knee pain. Patient reported a preexisting history of arthritis in his right knee saying that he had been told he “had no cartilage left in his right knee.” X rays were ordered at the time of the visit but results were not available to the reviewer. Patient returned on 11/21/06 at which time his knee pain was intermittent and the back pain was mild. Patient had started physical therapy around this time. The patient did not return for more than 6 months (6/25/07) and back pain was still present but reportedly the knee pain had subsided. The note indicates that the patient was using a nerve stimulator at this time and it was to be continued. Next visit was 7/23/07 at which time patient continued to have low back pain but reported no knee pain. Patient was to continue the nerve stimulator for treatment. Final visit in notes was 8/21/07. Patient reported intermittent knee pain with long periods of walking and continued low back pain. Again it was reported that the patient would continue the nerve stimulator.

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.**

The reviewer agrees with the prior determination and does not find that the Bionicare knee device is medically necessary.

The patient was diagnosed with an acute lumbosacral strain and acute knee injury. Patient had a preexisting diagnosis of osteoarthritis of his right knee prior to this time.

The ODG guidelines support the use of office based physical therapy followed by a home exercise program for both of the above diagnoses. There is also evidence that a TENS unit may be beneficial for the short term treatment of knee arthritis and can be used for chronic lumbosacral pain. (Although studies quoted in ODG do not show benefit over placebo). The clinical notes indicate that the patient received both of the above treatments.

Since the Bionicare knee device was not mentioned in the ODG guidelines, the reviewer obtained two of the studies done with the device to help determine whether the device is medically necessary. The first study was published in Surgery Technology International, 2005. (Pulsed Electrical Stimulation in Patients with Osteoarthritis of the Knee: Follow up in 288 Patients who had Failed Non-Operative Therapy.) The study showed a significant improvement in all primary efficacy variables (patient global functioning, patient pain, physician assessment of global functioning) but there was a dose response seen. Usage of the machine for greater than 750 hours was accompanied by a greater frequency of 50% improvement in one or more variable. The study was done on patients who had moderately severe to severe arthritis who had not responded to other therapies. The study did not have a control group and was not blinded. The second study in Biomechanics, 2006 was titled Electrical Stimulation helps delay knee replacement surgery. This study looked at patients with severe knee arthritis who had been recommended by an orthopedic surgeon to have a knee replacement. There was a significant difference in the delay in time to surgery in

the test group as compared to controls. This device was used for on a daily long term basis (years).

The Bionicare knee device has been shown in the above studies to have effects on patients with moderate to severe osteoarthritis of the knee. The studies indicate that it is to be used for several months to years. The case reviewed involved an acute knee injury in a patient with preexisting arthritis (as well as a lumbosacral injury). From the available literature, it appears the Bionicare knee device is indicated for severe osteoarthritis to improve pain and functioning. This patient's clinical notes are not supportive of this degree of symptoms as the patient's pain is intermittent and does not seem to be causing a significant change in global functioning. Although the advertisement indicates it provides pain relief in as little as 4 weeks, the intention of the device appears to be long term use. It is not a device that has enough of a tract record to be considered standard of care. The reviewer does not find this device to be medically necessary in this case.

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE
  - Surgery Technology International and Biomechanics
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)