



Specialty Independent Review Organization, Inc.

March 16, 2005

Hilda Baker
TWCC Medical Dispute Resolution
7551 Metro Center Suite 100
Austin, TX 78744

Patient:
TWCC #:
MDR Tracking #: M2-05-0981-01
IRO #: 5284

Specialty IRO has been certified by the Texas Department of Insurance as an Independent Review Organization. The Texas Worker's Compensation Commission has assigned this case to Specialty IRO for independent review in accordance with TWCC Rule 133.308 which allows for medical dispute resolution by an IRO.

Specialty IRO has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed.

This case was reviewed by a licensed Medical Doctor who is board certified in Neurology. The reviewer is on the TWCC ADL. The Specialty IRO health care professional has signed a certification statement stating that no known conflicts of interest exist between the reviewer and any of the treating doctors or providers or any of the doctors or providers who reviewed the case for a determination prior to the referral to Specialty IRO for independent review. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

CLINICAL HISTORY

___ suffered a work-related injury on ___ when she was struck by a forklift. She was lifting cardboard boxes when she was struck in the left-hand side of her body by a forklift and was "pinned" under the forklift. She developed pain in her neck, upper middle back, lower back, rib cage, left shoulder, left arm, left elbow, left hip and left knee. She was evaluated by the paramedics at the scene of the accident and remained at work. According to a history obtained by Dr. Tom Rubio, a chiropractor, later on that day ___ went to Methodist Hospital where she had x-rays taken of her neck, upper and middle back and lower back. She was diagnosed with a sprain of her neck, sprain of the upper and middle back and sprain of the lower back and sprain of the left knee. There are no reports submitted from the Methodist Hospital Emergency Room.

She presented to Dr. Rubio on 12-02-03 with complaints of neck pain, upper back pain, mid-back pain, lower back pain, and shoulder and arm pain. She also had complaints of hip pain, leg pain and headaches. She had had a prior injury to the left knee in ___ for which she underwent ACL surgery.

Dr. Rubio's initial examination was significant for reduced left hip flexion and reduced left leg extension with normal sensation. In the thoracic region, there was spasm overlying the upper and lower areas on the left with tenderness in the midline. In terms of her left knee, she had positive valgus stress and popping at the medical component of her left knee and a negative drawer sign. Dr. Rubio's initial impression was:

1. Thoracic sprain/strain.
2. Lumbar pain.
3. Lumbar sprain/strain.
4. Cervical sprain/strain.
5. Thoracic pain/strain.
6. Internal derangement of the left knee.
7. Peripheral elbow sprain/strain.
8. Internal derangement of the shoulder.

He recommended adjustments of the left shoulder and left knee, adjunctive physical modalities including ice, moist heat, thermotherapy, ultrasound and interferential stimulation, plus exercise program for active range of motion and passive range of motion of the left knee. Unfortunately, ___' left knee pain did not improve with Dr. Rubio's care, so he referred her to Dr. McConnell, an orthopedist.

Dr. McConnell's initial consultation is not submitted, but he indicated in a follow-up note, which was dated 03-09-04 that she was experiencing left knee pain described as sharp, dull, throbbing, moderate to severe in nature, which was constant and exacerbated by activity. She received conservative treatments including NSAIDs and physical therapy for 2 months. She had a previous knee surgery and "wished to proceed" with left knee arthroscopy. Dr. McConnell's examination revealed a positive Apley's test with medial joint line tenderness present upon palpation and a mild effusion noted to the left knee with crepitation noted upon palpation with movement. She had a negative anterior and posterior drawer test and a negative valgus stress test. She tended to guard against all testing however. X-rays of the patient's left knee in 3 views including bilateral standing, lateral, and sunrise showed medial joint space narrowing with lipping and spurring of the distal femur and proximal tibia with chondromalacia patella present. There was no evidence of fracture or instability or foreign bodies.

Dr. McConnell recommended a knee arthroscopy, which was scheduled on 03-16-04. Unfortunately, after surgery she continued to have a fair degree of pain for which she received Vioxx 25-mg b.i.d. She was noted to have reduced range of motion of the left knee. She continued under the care of Dr. Rubio and physical therapy.

Records also indicate that ___ was seen by Dr. Joe Coleman on 08-13-04 for the purpose of an impairment rating. His impression was postsurgical meniscus tear, partial thickness tear supraspinatus left shoulder and mild lumbar spinal canal stenosis. He gave ___ a 5 percent impairment rating for her injured left knee and a total person impairment of 8 percent. He felt she was at MMI as of 08-13-04. Also, Dr. Audrey Goldings, a neurologist, saw ___ on August 16, 2004 for a maximal medical improvement exam. Dr. Goldings gave her a 1 percent whole person impairment based upon her current work related injury of her knee and lower back.

A medical necessity review was performed on March 1, 2005 by Dr. Richard Levy an orthopedic surgeon. The purpose of this review was to evaluate the need for additional therapy. According to Dr. Levy's report, ___'s length and frequency of treatment were excessive. In his opinion, after the surgery of March 23 2004, she should have required approximately 3 weeks of supervised physical therapy followed by a home exercise program. He felt that the records did not support the need for any treatment, diagnostic testing, medication, herbal medical equipment or physical therapy. The extent of injury appears to be posterior horn medial-meniscus injury. There was no need for any injections.

___ was evaluated by Robert Freedenfeld, PhD a clinical psychologist on April 13, 2004 because of her depression, anxiety and pain. Dr. Freendenfeld's diagnostic impression was: Axis I: pain disorder associated with both psychological factors and a general medical condition, chronic and major depressive episode, single episode, severe without psychotic features. Axis IV included moderate stressors including significant restriction physical and social activities, unemployment and financial distress. Axis V GAF was 55 (current). Dr. Freedenfeld recommended individual psychotherapy.

___ underwent a Functional Capacity Evaluation on 08-02-04, which indicated that the assessment was thought to be valid. She had no nonorganic physical signs when tested. She had slightly reduced range of motion of the left knee. The findings indicated that she could function at a sedentary level of activity.

Test results submitted included an MRI of the left knee performed on 01-05-04. This showed medial and lateral compartment degenerative changes, plus a posterior horn of the medial meniscus intrameniscal degenerative signal, but no frank meniscal tearing. Postoperative changes were noted in the proximal attachment of the anterior cruciate ligament. There was scarring in Hoffa's fat likely related to prior surgery. An MRI of the lumbar spine, showed a mild to moderate degree of central canal stenosis at L4-5 due to generalized disk bulging and a moderate degree of bilateral facet joint hypertrophy and ligamentum flavum thickening. There was disk desiccation at L1-2 and L4-5 levels and mild bilateral facet joint hypertrophy at L5-S1. An MRI of the left shoulder showed a low to moderate grade partial thickness tear of the supraspinatus tendon and moderate acromioclavicular joint degenerative capsular hypertrophy, which contacted the suprahumeral cuff in the neutral position. There was also anterior labral tearing.

Records reviewed:

1. Office progress notes Tom Rubio, DC dated 11-26-03 through 03-09-04.
2. Office progress notes and TWCC documents McConnell Orthopedic Clinic, John McConnell, MD dated 03-09-04 through 02-15-05.
3. Operative report, Park Central Surgery Center, John McConnell, MD, March 23, 2004.
4. Medical consultation James W. Galbraith, MD dated January 26, 2004.
5. Impairment evaluation Dr. Joe Coleman 08-13-04.
6. Maximum medical improvement exam Audrey Goldings, MD August 16, 2004 plus clarification October 4, 2004.
7. Medical Necessity Review Richard S. Levy, MD March 1, 2005.
8. Initial mental health status evaluation and individual psychotherapy progress notes Robert S. Freedendfeld, PhD dated April 13, 2004 through July 13, 2004.
9. Treatment and Progress notes, authorship unknown 03-11-04 through 01-14-05.
10. Functional capacity evaluation signature illegible 08-02-04.
11. Letter addressed to TWCC Dallas, Tom Rubio, DC dated August 31, 2004.
12. Bio-1000 prescription, John McConnell, MD, dated 11-23-04.
13. Denial letter addressed to BioniCare Inc. dated 01-21-05, Intracop.
14. Statement of medical necessity/letter of medical necessity, BioCare Bio-1000, John McConnell, MD dated 11-23-04.
15. Product description, BioniCare Bio-1000 system.

REQUESTED SERVICE

The item in dispute is the prospective medical necessity of a Bio-1000 system.

DECISION

The reviewer agrees with the previous adverse determination.

BASIS FOR THE DECISION

The BioniCare 1000 system consists of application of pulsed electrical stimulation to the knee for relief of symptoms of arthritis. The only available clinical literature regarding this product consists of a single poster presentation from the American Academy of Orthopedic Surgeons presented on March 10, 2004. This was a study using 157 patients with osteoarthritis of the knee who were treated and pulsed with electrical stimulation to the knee for 3 months. These patients were compared to a "matching group of 100 patients with osteoarthritis of the knees. Both groups were followed yearly until 4 years". Please note there was no blinding done. There was no sham stimulation performed. The results were that the electrically stimulated patients had a tendency towards avoiding knee arthroplasty and a p value of 0.0004 is quoted. The conclusion was that the study demonstrated that pulse electrical stimulation was a safe and effective method for avoiding total knee arthroplasty as well as relieving clinical signs and symptoms of osteoarthritis of the knee.

The reviewer states that this study is of dubious scientific merit. It is not blinded and is therefore subject to both investigator and subject bias. There is no comparison of the pathology, age, or other treatment modalities between the treatment group and the control group. Also, this application does not apply to patients such as ___ who has now had 2 knee surgeries. Her condition is not that of simple knee osteoarthritis, but rather now she has had 2 invasive procedures performed on her knee. There is no evidence that this device would be of benefit in a patient such as ___ as there have been no studies indicating use of the Bio-1000 system in patients with prior knee surgery. ___ does not have straightforward “osteoarthritis” of the knee but a chronic pain disorder status post knee surgery times two. There are no other clinical studies available in the medical literature, which are available through multiple web search engines and medical literature searches.

References:

The, D, L. Jones, K. Hoffman-Parkton, D. Hungerford, T. Zizic and M. Mont. The use of electrical stimulation to avoid total knee arthroplasty. Presented as a poster, American Academy of Orthopedic Surgeons annual meeting March 10-14, San Francisco, California.

Specialty IRO has performed an independent review solely to determine the medical necessity of the health services that are the subject of the review. Specialty IRO has made no determinations regarding benefits available under the injured employee’s policy. Specialty IRO believes it has made a reasonable attempt to obtain all medical records for this review and afforded the requestor, respondent and treating doctor an opportunity to provide additional information in a convenient and timely manner.

As an officer of Specialty IRO, Inc, dba Specialty IRO, I certify that there is no known conflict between the reviewer, Specialty IRO and/or any officer/employee of the IRO with any person or entity that is a party to the dispute.

Sincerely,

Wendy Perelli, CEO

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.

In the case of prospective *spinal surgery* decision, a request for a hearing must be made in writing and it must be received by the TWCC Chief Clerk of Proceedings within **10** days of your receipt of this decision. (20 Tex. Admin. Code 142.5(c)).

In the case of other *prospective (preauthorization) medical necessity* disputes 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 (28 Tex. Admin. Code 148.3).

This decision is deemed received by you 5 (five) days after it was mailed (28 Tex. Admin. Code 102.4(h) or 102.5(d)). A request for a hearing should be sent to: Chief Clerk of Proceedings, Texas Worker's Compensation Commission, P.O. Box 17787, Austin, TX 78744. The fax number is 512-804-4011. A copy of this decision should be attached to the request.

The party appealing this decision shall deliver a copy of its written request for a hearing to all other parties involved in the dispute, per TWCC rule 133.308(u)(2).

Sincerely,

Wendy Perelli, CEO

I hereby certify, in accordance with TWCC Rule 102.4 (h), that a copy of this Independent Review Organization decision was sent to the carrier, requestor, claimant (and/or the claimant's representative) and the TWCC via facsimile, U.S. Postal Service or both on this 17th day of March 2005

Signature of Specialty IRO Representative:

Name of Specialty IRO Representative: Wendy Perelli