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Notice of Independent Review Decision

MEDICAL RECORD REVIEW:

DATE OF REVIEW: 10/26/2010

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified) Doctor, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

60-day rental of knee/ankle flexionater between 9/16/10 and 11/15/10

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o 05-14-10 History and Physical Examination from Dr.
- o 05-16-10 Progress report from Dr.
- o 08-19-10 Knee Evaluation from Dr. and the therapist
- o 09-03-10 Treatment Encounter Note from PT
- o 09-03-10 10 medical reports from Dr. from 05-28-10 to 09-03-10
- o 09-07-10 Approximate date for Knee/Ankle Flexinator use instructions and ODG citations
- o 09-07-10 Approximate date for misc. coding information for the flexinator from unsigned
- o 09-07-10 Certificate of Medical Necessity from Dr. (?)
- o 09-17-10 Initial adverse determination letter
- o 09-17-10 Peer review
- o 09-22-10 Letter of appeal
- o 10-01-10 Reconsideration - adverse determination letter
- o 10-01-10 Peer Review determination for reconsideration
- o 10-05-10 Request for IRO from the Claimant
- o 10-05-10 Confirmation of Receipt of Request for IRO from TDI
- o 10-06-10 Treatment Encounter Notes from the therapist 8-19-10 to 10-06-10 (illegible signature)
- o 10-06-10 PT flow sheet covering 8-9-10 to 10-06-10 - 16 visits from illegible
- o 10-06-10 PT progress report from the therapist and Dr.
- o 10-07-10 Notice to P&S of Case Assignment from TDI
- o 10-11-10 Fax cover sheet for IRO request from Orthopedics
- o 10-13-10 Fax cover sheet for additional information from

PATIENT CLINICAL HISTORY (SUMMARY):

According to the medical records and prior reviews the patient is a female who sustained an industrial injury to the left leg on xx/xx/xx associated with a slip and fall in a parking lot. She is status post ORIF for a left distal femur comminuted fracture. Co-morbid conditions include diabetes mellitus and hypertension.

Per the history and examination of the patient works in a and lives in a single story home. She is in an extension brace with a drain still in place. She relates pain at the left thigh with some swelling. There is a fair amount of thigh and foot swelling seen. The surgical dressing was removed. Impression is impaired gait after a left femur fracture. She had an ORIF and is non-weight bearing on the left. She was anemic and required transfusion of packed red blood cells. She will initiate inpatient rehab.

Although the patient has diabetes and is overweight, a bone stimulator requested on June 17, 2010 was initially denied.

Post-op x-rays on June 18, 2010 two months post-op show no significant callus formation compared with the prior month study. The repaired fracture is likely developing into a delayed versus nonunion.

On August 13, 2010 the patient is using a bone stimulator and is compliant with non-weight bearing. She is wearing the brace and working part-time. An order is written for PT.

The patient was assessed in PT on August 19, 2010. Active right knee ROM is flexion to 55 degrees and extension of -8 degrees. Hamstring flexibility is within normal limits. Quad tone and setting ability is poor on the right (2/5). Left SLR ability and VMO tone is fair (3/5). Patellar mobility is normal on the right. Short-term goals include increasing ROM to -4 to 80 degrees with better mechanics and gait. Long-term goal is to achieve motion of -1 to 95 degrees. Prognosis is good.

On September 3, 2010 the patient is weight bearing 25% of the time with no problems reported.

The PT notes of September 3, 2010 note compliance with HEP. A certificate of medical necessity of the same date notes knee flexion as 55 degrees.

Medical report of September 27, 2010 indicates the patient is four months out from ORIF left femur. She has been using a T-scope knee brace, except during therapy. She reports doing well overall with some persisting stiffness. She is developing shoulder problems from use of the walker. Knee flexion is to 45 degrees. X-rays show no signs of hardware loosening. Abundant callus formation is lacking.

Appeal letter dated September 22, 2010 was submitted. The patient has 55 degrees of knee flexion, far from her goal of 130 degrees. She continues to have pain with weight bearing activities and any flexed position of the knee, and she complains of limitation with her ADLs. Her ROM and gait deficits resulted in an impairment rating of 34%. These impairments are treatable. The flexinater was ordered to help this patient improve her motion, restore her gait and avoid additional surgery. There are no comparable devices from other manufacturers or distributors that provide the high intensity stretch necessary to treat her condition. The ERMI device is her best change for a favorable outcome. Product information is provided: Per the provider the Knee Flexinater (KF) is a patient-actuated serial stretch device used in the patient's home as an adjunct to PT to help improve motion. The KF is a high-intensity ERMI device which applies a load to the joint that more closely replicates the force applied by a physical therapist. Cost savings reports and orthopedic articles are cited. Attached product information indicates the flexinater is recommended when "there are signs of significant motion stiffness/loss in the sub-acute injury or post-operative period - at least 3 weeks after injury or surgery." In one study (Dempsey et. Al 2010), knee extension was initially improved 10.4 degrees to 2.4 degrees after 3 months. 2.2 degrees was maintained at follow-up.

Request for 60-day rental of knee/ankle flexionater between 9/16/10 and 11/15/10 was considered in review on September 17, 2010 with recommendation for non-certification. 11 pages of medical records were reviewed. Per the reviewer, the patient underwent an ORIF of a femur fracture on May 12, 2010. She failed to regain ROM after the surgery. ODG states flexionaters are currently under study secondary to a lack of scientific evidence to support the efficacy of the treatment. On this basis, the request is denied.

Request for reconsideration 60-day rental of knee/ankle flexionater between 9/16/10 and 11/15/10 was considered in review on October 1, 2010 with recommendation for non-certification. A discussion took place with an assistant of the provider and she was unable to provide additional information to substantiate the request. The patient underwent ORIF of the femur on May 12, 2010. On August 19, 2010 he was reported to have restricted ROM and motor weakness. On September 22, 2010 she has knee flexion of 55 degrees. She has pain with weight bearing activities and any flexed position of the knee. She has a WPI of 34 % based on lost ROM. Knee flexionater was ordered to help with knee ROM, restore gait and avoids a repeat surgery. Report of August 19, 2010 notes pain from 2-4/10 and a shoulder problem. Active extension is -8 degrees and flexion is 55 degrees. She has poor quad setting ability and poor quad tone. Per the reviewer, the submitted records did not provide the specific functional goals for the requested knee/ankle flexionater. Moreover, this form of treatment is still under study. There is a lack of scientific evidence regarding the effectiveness of the knee/ankle flexionater.

PT progress report dated October 6, 2010 notes the patient is progressing well but slowly and would benefit from some continued therapy for increased ROM, gait and strengthening. Her pain level is 4/10 at the knee and 6/10 at the thigh. She can tolerate standing for 15 minutes and walking for 5-10 minutes. Right knee flexion is to 85 degrees.

Request was made for an IRO.

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

Per ODG, flexionators are under study. There is a lack of scientific evidence regarding the effectiveness of the knee/ankle flexionator, the shoulder flexionator, the knee extensionator, and the elbow extensionator. The knee flexionator is designed to address the needs of patients with arthrofibrosis (excessive scar tissue within and around a joint) by using a variable load/variable position device that uses a hydraulic pump and quick-release mechanism to allow patients to perform dynamic stretching exercises in the home without assistance, alternately stretching and relaxing the scar tissue surrounding affected joints... There is insufficient scientific evidence to support the manufacturer's claims that these home-based stretching devices can consistently stretch scar tissues without causing vascular re-injury and thus significantly reduce the need for additional surgery.

On August 19, 2010 short-term PT goals include increasing ROM from -8/55 degrees to -4/80 degrees. Per a study cited by the provider as noted above, long-term improvement of knee motion was noted of 2.2 degrees using the flexionator after 3 months treatment; far less than anticipated by the therapist with PT. The DME information also noted that it is recommended for use when there are signs of significant motion stiffness/loss "in the sub-acute injury or post-operative period - at least 3 weeks after injury or surgery." The patient is 5 months post surgery. Given the caution per ODG noting there is insufficient scientific evidence to support the manufacturer's claims that these home-based stretching devices can consistently stretch scar tissues without causing vascular re-injury and thus significantly reduce the need for additional surgery, this treatment cannot be supported.

Therefore, my recommendation is to agree with the previous non-certification of the request for 60-day rental of knee/ankle flexionator between 9/16/10 and 11/15/10.

The IRO's decision is consistent with the following guidelines:

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

AHCP- 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

(PROVIDE A DESCRIPTION)

_____ OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME

The Official Disability Guidelines 09-24-2010 Knee and Leg Chapter: Flexionators (extensionators):

Under study. There is a lack of scientific evidence regarding the effectiveness of the knee/ankle flexionator, the shoulder flexionator, the knee extensionator, and the elbow extensionator. The knee flexionator is designed to address the needs of patients with arthrofibrosis (excessive scar tissue within and around a joint) by using a variable load/variable position device that uses a hydraulic pump and quick-release mechanism to allow patients to perform dynamic stretching exercises in the home without assistance, alternately stretching and relaxing the scar tissue surrounding affected joints. The knee extensionator provides serial stretching, using a patient-controlled pneumatic device that can deliver variable loads to the affected joint. There are no controlled published peer-reviewed studies on the effectiveness of the knee/ankle flexionator, the shoulder flexionator, the knee extensionator, or the elbow extensionator. There is insufficient scientific evidence to support the manufacturer's claims that these home-based stretching devices can consistently stretch scar tissues without causing vascular re-injury and thus significantly reduce the need for additional surgery (e.g., surgery for arthrofibrosis after knee surgery). Furthermore, there is a lack of published data to support the claim that these devices can reduce the need for manipulation under anesthesia. (Aetna, 2010) (Branch, 2003) A retrospective study using claims data sponsored by the manufacturer, ERMI, concluded that patients with knee arthrofibrosis treated with high intensity stretch (the ERMI device) had reduced subsequent medical costs, compared to low intensity stretch or physical therapy alone. Among the study limitations are that (1) medical claims with codes relating to knee device use were not included as part of costs; (2) the ERMI cohort was only 0.2% of the total cohort; (3) patients treated with the low intensity device had significantly more musculoskeletal disease upfront than ERMI patients; (4) while the PT-only group had slightly greater costs relative to the ERMI group, the increase was "not statistically significant"; (5) the single factor with the greatest effect on post-index costs was the presence of total knee arthroplasty as the index event, and the three groups differed greatly in the incidence of arthroplasty, with 46.3% of the low intensity group, 19.0% of the no device group, and only 11.9% of the ERMI group having this procedure as their index event. (Stephenson, 2010) Using an instrumented test leg (not real patients, hence the lower rating), this study reported that ERMI high-intensity devices provided loads that more closely replicate the force applied by a physical therapist, whereas low-intensity devices including dynamic splints and SPS devices provide loads similar to those provided by common home exercises. The affect on patient outcomes is unclear, as well as real patient tolerance to the increased force, and patient compliance with the self-directed therapy. (Uhl, 2010)