

AccuReview

An Independent Review Organization

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Notice of Independent Review Decision

[Date notice sent to all parties]: June 30, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

ERMI Knee Flexinator E1399, 30 Day Rental, \$115.50/Day

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

This physician is a board certified Orthopaedic Surgeon with over 13 years of experience.

REVIEW OUTCOME:

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

Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

03-06-13: Office Visit

03-22-13: Office Visit

03-29-13: Office Visit

04-09-13: Progress Note

04-09-13: Office Visit

04-15-13: Office Visit

04-17-13: Certificate of Medical Necessity

04-24-13: Office Visit at Medical Centers

04-30-13: UR performed

05-10-13: Letter of Medical Necessity

05-15-13: Office Visit at Medical Centers

05-17-13: Office Visit at Medical Centers

05-20-13: Notes

05-20-13: Patient Referral at Medical Centers

06-03-13: UR performed

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who reported an injury on xx/xx/xx when he was climbing a ladder and fell 18 feet on left leg. He was diagnosed with a femur fracture. The claimant went on to intermedullary rodding of a femur fracture, as well as, a complete patellectomy on 1/25/13.

03-06-13: Office Visit. Surgical Procedure: Left femur intramedullary nailing fracture left patellectomy. Claimant presented with decreased ROM and stability of the left knee that is aggravated by increased movement and weight bearing, and eased by rest and medication. Objective: Gait: moderate antalgic gait with stiff knee and decreased weight bearing. Knee AROM: Flex: 30, Ext: 0. Knee Strength involved knee: flex: 3-, ext: 3-. Flexibility: NT secondary to pain and protocol. Palpation: Claimant has tenderness to palpitation around the incision sites that are healing well. Observation: Transitional Movements: claimant displays mildly guarded transitional movements. Treatment given: HEP has been explained and demonstrated by claimant. The claimant examination is consistent with the medical diagnosis of Femoral Fracture, Patella Fracture. Impairment List: AROM, PROM, Pain, Muscle Performance, Joint Mobility. Functional Restrictions: unable to climb stairs, abnormal gait, unable to squat, limited knee ROM, unable to lift floor to waist, unable to push/pull. Prognosis: Claimant's symptoms should resolve with therapy and a home exercise. Goals: within 3-6 visits: 1. Pt independent with HEP, 2. ROM and Strength to WNLs, 3. Normalize Gait and Balance, 4. Decrease Edema, 5. Able to lift and carry 40# (floor to waist), 6. Able to push/pull 50#, 7. Demonstrate Safe/Efficient Reg Duty Abilities. Impairment Goals: AROM: initial value: 30; Current value: 30; Goal 135. Muscle performance knee flexion: Initial value: 3-/5; Current value: 3-/5; Goal: 5/5; Goal status: not addressed in this visit. Pain: initial value: 5; Current value: 5; Goal: 0. Plan: Frequency:3 x week Duration: 4 weeks.

04-09-13: Progress Note. Objective: Pain 2/10. Gait: moderate antalgic gait with stiff knee and decreased weight bearing using bilateral crutches. Sensation: intact to light touch. Knee AROM: Involved knee: flex: 52, ext: 0. Knee strength: Involved knee: flex: 3+, ext: 3+. Flexibility: NT secondary to pain and protocol. Assessment: Claimant tolerated PT RX with minimal C/O pain. Claimant requires continued skilled intervention to decrease pain, improve function, increase ROM, increase strength to premorbid levels. Claimant demonstrates HEP with 100% comprehension and has been educated regarding their diagnosis, prognosis, related pathology and plan of care. Overall Progress: as expected. Plan: Continue to strengthen and stretch as tolerated by pt, continue plan of care using therapeutic exercise, neuromuscular re-education, therapeutic activity, manual therapy, and modalities as needed.

04-15-13: Office Visit. Chief complaint: left femur pain. His pain level is 4/10 and he has difficulty with ROM and is currently in physical therapy, currently using crutches. PE: Shows a well-healed incision anteriorly over the knee and hip laterally. He has a negative log roll. He has hip flexion 90, external rotation 30,

and internal rotation in 10 with some mild pain. He has got full extension without extensor lag. He has flexion to 70 degrees. Normal neurovascular exam on the foot. Normal sensation. A 2+ DP pulse. X-Ray: X-Rays show a healing hip fracture and a complete patellectomy of the knee. Good position of the nail. Impression: Hip fracture and patellar fracture. Plan: Recommend physical therapy for range of motion exercises and weight bearing as tolerated. He may wean off crutches. He needs to return for follow up within one month.

04-24-13: Office Visit. Subjective: Claimant reported that he is not working because his employer is unable to accommodate modified activity. Objective: Knee AROM: Involved knee: flex: 70, ext: 0. Knee strength: Involved knee: flex: 4-, ext: 3+. Flexibility: NT secondary to pain and protocol. Assessment: Claimant tolerated PT RX with minimal C/O pain. Claimant requires continued skilled intervention to decrease pain, improve function, increase ROM, increase strength to premorbid levels. Claimant demonstrates HEP with 100% comprehension and has been educated regarding their diagnosis, prognosis, related pathology and plan of care. Overall Progress: as expected. Plan: Continue to strengthen and stretch as tolerated by pt, continue plan of care using therapeutic exercise, neuromuscular re-education, therapeutic activity, manual therapy, and modalities as needed.

04-30-13: UR performed. Reason for denial: The request for ERMI knee Flexionater E1399, thirty day rental \$115.50/day is non-certified. This claimant is a male who reported an injury on xx/xx/xx. The documentation submitted for review indicates that the claimant suffered patellar and hip fractures after a fall onto the claimant's left leg. The documentation submitted for review also details the claimant underwent surgical intervention for a left femur fracture, as well as, a patellectomy. The most recent evaluation of the claimant in physical therapy detailed range of motion of the left knee from 0 degrees to 60 degrees with strength and flexion of 4-/5 and extension of 3+/5. Subjective complaints of the claimant include pain verbalized as 4/10 with difficulty on range of motion. Physical examination of the claimant detailed a well-healed incision anteriorly over the knee and hip laterally. Notes detail hip flexion of 90 degrees, external rotation 30 degrees, external rotation 30 degrees, and internal rotation to 10 degrees with mild pain. The claimant had full extension of the knee without extensor lag and 70 degrees of flexion. Plan as tolerated. The ODG guidelines detail recommendation of a flexionator as an option in conjunction with continued physical therapy for 6 weeks if PT alone had been unsuccessful and adequately correcting range of motion limitations secondary to post-operative fibrosis within 3 months of major surgery. However, there is a lack of documentation indicating that the claimant currently has excessive scar tissue within or around knee joint. Also, there was a lack of documentation indicating a clear clinical rationale for the necessity of any flexionator or the medical necessity. As such, the request for ERMI knee flexionator E1399, thirty day rental \$115.50/day is non-certified.

05-10-13: Letter of Medical Necessity. Due to significant loss of left knee range of motion, the claimant is being hindered from his ability to achieve full right lower extremity strength and function in physical therapy. He is currently unable to: get

in/out of his vehicle, squat, go up or down a flight of stairs, drive, or kneel; has extreme difficulty standing for an hour and picking up objects from the floor. These activities are essential – not only for working purposes but him to return to his activities of daily living. Given the claimant's continued left knee range of motion restrictions, I am prescribing the ERMI Knee Flexionator for 60 days of use in conjunction with continued physical therapy. These devices should help this patient achieve a minimum of 25% gain in the left knee range of motion is gained, and assist with the patient's progress in performing the above mentioned essential job tasks in order to return to work as quickly, and safely, as possible.

05-17-13: Office Visit. Claimant is re-evaluated due to end of prescription and on Monday 5/20/13 he will complete prescribed number of treatments. Subjective: Claimant reported feeling 35% better since he started PT. He stated that after walking 1.5 to 2 hours the pain in his knee and hip starts and also after being sitting for awhile he feels pain in his hip. Activity restrictions: no restrictions. Objective: Knee AROM: Involved knee: flex: 76, ext: 2. Knee Manual Muscle Testing: Involved knee: flex: 3+/5, due to lack of ROM, ext: 4+/5. Assessment: The claimant's examination is consistent with the medical diagnosis of Femoral Fracture, Patella Fracture. Overall Progress: as expected. Plan: Consult referring doctor.

05-20-13: Notes. Claimant is doing much better and is in physical therapy. He is 4 months out from his surgery. Physical exam shows a well-healed incision anteriorly, no effusion with ROM from 0-70. He has a 3-degree extensor lag and ambulates with a cane with mildly antalgic gait. Impression: Resolving knee injury, status post patellectomy. Plan: Recommend aggressive physical therapy and activities as tolerated. Follow up in one month.

06-03-13: UR performed. Reason for denial: The claimant was injured on xx/xx/xx when he fell from a ladder and suffered a femur fracture. The claimant went on to intermedullary rodding of a femur fracture, as well as, a complete patellectomy. He had participated in physical therapy and had been unable to regain flexion of the knee. Flexion of the knee on March 6, 2013, was to 30 degrees. A reevaluation on April 9, 2013, documented a range of motion of the knee from 0-60 degrees. The clinical evaluated the claimant on April 15, 2013, and at that time range of motion was from 0-70 degrees in the knee. X-rays were stated to show healing of the fracture of the proximal femur and a complete patellectomy. The most recent objective physical examination findings were from May 15, 2013, and documented range of motion of the knee from 0-74 degrees following 28 physical therapy sessions. A letter of medical necessity from the clinician dated May 10, 2013, documented the claimant had significant loss of range of motion in the knee preventing activities of daily living with flexion only to 60 degrees. This is a non-certification of for an appeal of an ERMI knee Flexionator E1399 for a 30 day rental. The previous non-certification was due to lack of documentation of excessive scar tissue on the physical examination or a clear clinical rationale for the request. The previous non-certification is supported. No additional records were presented to be reviewed other than the treating provider's request letter for durable medical equipment due

to lack of range of motion of the injured employee's knee. Guidelines do support the use of a Flexionator device provided there are findings of post-operative arthrofibrosis or excessive scar tissue within or around a joint within three months of major knee surgery. This device is supported in conjunction with physical therapy and not as an isolated treatment. Records reflect surgical intervention was performed on January 25, 2013, and therefore the claimant is outside the three month range. The device is not being requested in conjunction with physical therapy. The claimant is noted to have loss of range of motion of the knee but at this time it is not felt a Flexionator would be of benefit this far out from surgical intervention. The request for an appeal of an ERMI knee Flexionator E1399 for a 30 day rental is not certified.

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

After review of the medical records and documentation provided, the previous adverse determination is upheld and agreed upon. The claimant does not require a Flexinator device at the present time. The Official Disability Guidelines (ODG) recommends the Flexinator for postoperative arthrofibrosis within the first three months of surgery. The first three months after surgery has already elapsed, leaving this device with potentially limited benefit for this patient. Furthermore, the claimant may not have true arthrofibrosis. His knee flexion is decreased, but there is no documentation of excessive scar tissue within the knee joint itself. The ODG supports this device for conditions in which knee motion has reached a "deficit plateau." Physical therapy has helped the patient regain significant knee flexion. His knee flexion improved from 30 degrees following surgery to 70 degrees in the postoperative period. Additional therapy may continue to increase knee flexion without the need for an external device. Based on the medical record reviewed, I am not convinced that the patient has reached a "deficit plateau." In conclusion, the request for ERMI Knee Flexinator E1399, 30 Day Rental, \$115.50/Day is denied.

Per ODG:

Flexionators (extensionators)	Recommended as an option in conjunction with continued physical therapy if 6 weeks of PT alone has been unsuccessful in adequately correcting range of motion limitations secondary to postoperative arthrofibrosis (excessive scar tissue within and around a joint), within 3 months of major knee surgery. The specific ROM limitations would be those causing functional limitations in return to work, ongoing patient compliance with the device needs to be documented, and device rental would be preferred. See also Physical medicine treatment . High-intensity stretch mechanical flexionator/ extensionator therapy may be effective for those patients whose motion has reached a deficit plateau when treated with this normal course of physical therapy alone. (Dempsey, 2010) 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. (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
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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, 2011](#)) In this non-controlled study, high-intensity stretch (HIS) mechanical therapy using the ERMI Knee Extensionator was prescribed only for those patients whose motion had reached a plateau when treated with physical therapy alone after knee arthroplasty, and passive knee extension deficits improved from 10.5° at the initial visit to 2.6° at the 3 month visit. The study included some workers’ comp patients. ([Dempsey, 2010](#)) In this RCT treatment of postoperative arthrofibrosis with an high-intensity stretch home mechanical therapy device was more effective and resulted in significantly improved outcomes when compared with low-intensity stretch devices. ([Papotto, 2012](#)) See also [Continuous passive motion](#) (CPM); [Physical therapy](#).

Other guidelines, group health: Cigna does not cover patient-actuated serial stretch (PASS) devices (e.g., ERMI Knee, MPJ, or Elbow Extensionator, ERMI Knee/Ankle or Shoulder Flexionator) for any indication because they are considered experimental, investigational or unproven. There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of their use for the treatment of joint stiffness or contractures. There is no evidence that these devices are comparable to established treatment methods. ([Cigna, 2010](#)) The use of patient actuated serial stretch devices, such as the ERMI Extensionator and Flexionator, for the treatment of joint contractures of the extremities alone or combined with standard physical therapy is unproven. Clinical evidence is not sufficient to demonstrate that they improve long-term patient outcomes, and studies lack comparison to other treatment modalities. ([United, 2011](#)) Patient-actuated serial stretch devices such as the ERMI Flexionator or Extensionator are considered not medically necessary. ([BlueCross, 2010](#)) Aetna considers the knee/ankle flexionator, the shoulder flexionator, the knee extensionator, and the elbow extensionator experimental and investigational because of a lack of scientific evidence of the effectiveness of these devices. ([Aetna, 2011](#))

Other guidelines, workers’ comp: The ERMI Flexionator and Extensionator is not covered by workers compensation in the State of Washington. ([LNI, 2011](#))

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 (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**