



**MEDICAL EVALUATORS
OF TEXAS ASO, LLC.**

2211 West 34th St. • Houston, TX 77018
800-845-8982 FAX: 713-583-5943

Notice of Independent Review Decision

DATE OF REVIEW: October 9, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

30-Day Rental of ERMI Knee Extensionater E1399 Left Knee

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

This case was reviewed by a physician who holds a board certification in Orthopedic Surgery and is currently licensed and practicing in the state of Texas.

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)

EMPLOYEE CLINICAL HISTORY [SUMMARY]:

The patient is a male with a history who hyper-extended his knee that resulted in an ACL and LCL tear of the left knee on as a result of a work injury on xx/xx/xx. He underwent ACL reconstruction on 05/23/2014. He has received treatment in the form of a knee brace, assistive device for ambulation, decreased weight-bearing, flexionator, home exercise program and physical therapy. Per a physical therapy note on 07/02/2014, the left knee range of motion was noted at -25 degrees to neutral on extension and 60 degrees on flexion. On 07/19/2014, a prescription note, he had 6- degrees of flexion. He was recommended with a knee flexionator. According to a physical therapy note on 07/23/2014, the patient completed 7 of 24 authorized sessions and had not yet completed the remaining 17 sessions. He was using a flexionator at home with good results. A progress note on 07/30/2014 indicates the patient is two months post-op. He has been attending physical therapy and has made some progress maintaining 95 degrees of flexion in therapy. Objective findings on examination of the left knee reveals he lacks approximately 5 degrees of full extension and flexes to approximately 85 degrees. He has



**MEDICAL EVALUATORS
OF TEXAS** ASO, LLC.

2211 West 34th St. • Houston, TX 77018
800-845-8982 FAX: 713-583-5943

negative Lachman's and anterior drawer test. The knee is stable to varus stress, full extension and 30 degrees of flexion. There is swelling along the distal portion of the lateral incision. There is no return of his peroneal nerve.

The request for a 30-day rental of ERMI Knee Extensionater was non-certified. As per the ODG, the extensionator is recommended within three months of major surgery, in conjunction with continued physical therapy. If six weeks of physical therapy alone has been unsuccessful in adequately correcting the range of motion limitations due to postoperative arthrosis then the extensionator is deemed medically necessary. The patient had not completed his full course of physical therapy, therefore the request is non-certified.

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

This is a male who underwent a massive left knee reconstruction including ACL and posterolateral corner reconstruction. He also has a complete peroneal nerve palsy per documentation and underwent peroneal neurolysis at time of index surgery. On my review of physical therapy documentation, therapy visits initiated on 07/02/2014. The last physical therapy documentation from 08/18/2014 demonstrates progression to 100° flexion, no peroneal recovery, and lacking of terminal extension. This therapy note also recommends additional 4 weeks of PT 3x/week. A request has been placed for a 30-day rental of the knee extensionator device to help restore terminal extension. On my review of the documentation, this request is medically necessary as per ODG criteria as he has undergone 6 weeks of physical therapy without resolution of his flexion contracture. This is devastating, likely career ending injury for this athlete, and I would support use of this device to aid in his lengthy recovery.

ODG – Knee & Leg (Acute and Chronic)

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



MEDICAL EVALUATORS OF TEXAS ASO, LLC.

2211 West 34th St. • Houston, TX 77018
800-845-8982 FAX: 713-583-5943

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 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



MEDICAL EVALUATORS OF TEXAS ASO, LLC.

2211 West 34th St. • Houston, TX 77018
800-845-8982 FAX: 713-583-5943

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)

Durable medical equipment (DME)

Recommended generally if there is a medical need and if the device or system meets Medicare's definition of durable medical equipment (DME) below. Most bathroom and toilet supplies do not customarily serve a medical purpose and are primarily used for convenience in the home. Medical conditions that result in physical limitations for patients may require patient education and modifications to the home environment for prevention of injury, but environmental modifications are considered not primarily medical in nature. Certain DME toilet items (commodes, bed pans, etc.) are medically necessary if the patient is bed- or room-confined, and devices such as raised toilet seats, commode chairs, sitz baths and portable whirlpools may be medically necessary when prescribed as part of a medical treatment plan for injury, infection, or conditions that result in physical limitations. Many assistive devices, such as electric garage door openers, microwave ovens, and golf carts, were designed for the fully mobile, independent adult, and Medicare does not cover most of these items. See also specific recommendations here: Aquatic therapy; Bathtub seats; BioniCare® knee device; Bone growth stimulators; Braces; Canes; Cold/heat packs; Compression cryotherapy; Continuous-flow cryotherapy; Continuous passive motion (CPM); Crutches; Cryocuff; Cryotherapy; Dynamic splinting systems; Dynasplint; Electrical stimulators (E-stim); Electromyographic biofeedback treatment; ERMI knee Flexionator®/ Extensionator®; Flexionators (extensionators); Exercise equipment; Game Ready™ accelerated recovery system; Home exercise kits; Joint active systems (JAS) splints; Knee brace; Lymphedema pumps; Mechanical stretching devices (for contracture & joint stiffness); Motorized scooters; Neuromuscular electrical stimulation (NMES devices); Orthoses; Post-op ambulatory infusion pumps (local anesthetic); Power mobility devices (PMDs); RS-4i sequential stimulator; Scooters; Shower grab bars; TENS (transcutaneous electrical nerve stimulation); Therapeutic knee splint; Treadmill exerciser; Unloader braces for the knee; Vacuum-assisted closure wound-healing; Vasopneumatic devices (wound healing); Walkers; Walking aids (canes, crutches, braces, orthoses, & walkers); Wheelchair; Whirlpool bath equipment.

The term DME is defined as equipment which:

- (1) Can withstand repeated use, i.e., could normally be rented, and used by successive patients;
- (2) Is primarily and customarily used to serve a medical purpose;
- (3) Generally is not useful to a person in the absence of illness or injury; &
- (4) Is appropriate for use in a patient's home. (CMS, 2005)



**MEDICAL EVALUATORS
OF T E X A S ASO,LLC.**

2211 West 34th St. • Houston, TX 77018
800-845-8982 FAX: 713-583-5943

**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)