



Notice of independent Review Decision

Amended Review 12/06/10

DATE OF REVIEW: December 2, 2010

IRO Case #:

Description of the services in dispute:

Knee/Ankle Flexionator right ankle rental 60 days

A description of the qualifications for each physician or other health care provider who reviewed the decision

The physician who provided this review is board certified by the American Board of Orthopaedic Surgery. This reviewer completed a fellowship in Pediatric Orthopaedic Surgery which includes spinal surgery as well as extremities. This reviewer performs spinal surgery on a regular basis. This reviewer is a member of the American Academy of Orthopaedic Surgeons and the Pediatric Orthopaedic Society of North America. This reviewer has been in active practice since 2000.

Review Outcome

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

Based on ODG guidelines, the prior denials for a knee/ankle flexionator for the right ankle rental 60 days should be upheld.

Information provided to the IRO for review

Records Received from the State:

Notice to Medical Review Institute of America, Inc of Case Assignment, 12/02/10 (1 page)

Confirmation of Receipt of a Request for a Review by an Independent Review Organization, 11/11/10 (4 pages)

Request for a Review by an Independent Review Organization, 11/11/10 (2 pages)

Workers' Compensation Services, Notification of determination, 08/30/10 (3 pages)

Workers' Compensation Services, Prior review, 09/03/10 (3 pages)

Workers' Compensation Services, Prior review, 09/28/10 (3 pages)

Records Received:

Letter 09/21/10 (1 page)

Authorization request, 08/24/10 (4 pages)

Certificate of Medical Necessity, 08/17/10 (1 page)

Healthcare System, Patient registration form, 08/10/10 (1 page)

Healthcare System, Re evaluation, 08/03/10 (3 pages)

verification of patient benefits, 08/16/10 (1 page)

Email 08/20/10 (3 pages)

Article study, "Only ERMI's Products Offer a High-Intensity Stretch to Improve Joint Rehab and Increase Range of Motion" (1 page)

Article study, "ERMI products lower payer costs and improve Return to Work outcomes for patients with motion loss"

Article study, "ERMI knee/ankle flexionater"

Records Received from Orthopedics:

Texas Department of Insurance, Letter 11/12/10 (1 page)

MD, follow up note, 10/27/10 (1 page)

MD, follow up note, 09/15/10 (1 page)

MD, follow up note, 09/08/10 (1 page)

MD, follow up note, 09/03/10 (1 page)

MD, follow up note, 08/18/10 (1 page)

MD, follow up note, 07/21/10 (1 page)

MD, follow up note, 06/23/10 (1 page)

MD, follow up note, 06/04/10 (1 page)

MD, follow up note, 05/19/10 (2 pages)

Orthopedic Hospital, Operative report, 05/24/10 (2 pages)

Orthopedic Hospital, Consultation, 05/24/10 (2 pages)

Neurology Center, Electromyography, 09/01/10 (3 pages)

Letter MD, 05/25/10 (1 page)

Records Received :

Neurology Center, Procedure note, 09/01/10 (2 pages)

Neurology Center, Electromyography, 09/01/10 (3 pages)

Orthopedic Hospital, Anesthesia record, 05/24/10 (6 pages)

Orthopedic Hospital, Operative report, 05/24/10 (2 pages)

Clinic note, MD, 05/28/10 (2 pages)

Texas Workers' Compensation Work Status Report, 05/14/10 (1 page)

X-ray reports, 05/11/10 (6 pages)

Patient clinical history [summary]

The patient is a male now 6 months status post open reduction internal fixation (ORIF) of right triplane ankle fracture complicated by neurological damage and loss of ankle range of motion is indicated for an ankle stretching brace to improve range of motion. Electromyography suggests a moderate to severe lumbar plexopathy.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

The prior denials should be upheld. ODG specifically addresses the device and findings present in this case and reports that the device is not medically necessary.

A description and the source of the screening criteria or other clinical basis used to make the

decision:

ODG guidelines: 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)

ODG, Knee and Leg, Flexionators (extensionators)