INDEPENDENT REVIEWERS OF TEXAS, INC.

2150 S. Central Expressway · Suite 200-264 · McKinney, Texas 75070
Office 214-533-2864 Fax 469-219-3349
e-mail: independentreviewers@hotmail.com

06/25/2018
Amended Decision: 07/09/2018
IRO CASE #: XXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: ERMI shoulder flexionator, 30 day rental for use of left side

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: MD, Board Certified Orthopedic Surgeon

REVIEW OUTCOME:

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

X Upheld (Agree)

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is XX whose date of injury is XX. The mechanism of injury is described as while attempting XX, a shooting pain was felt in the left upper extremity and into the left shoulder. The patient underwent left shoulder arthroscopic rotator cuff repair and subacromial decompression on XX. Office visit note dated XX indicates that current medication is XX. On physical examination arthroscopic portals look good with no swelling or erythema. There is full movement of the elbow and hand. Neurovascular exam is normal. Plan of care dated XX indicates that the patient has completed 23 therapy visits to date. The patient has returned to working. Pain was rated as 1/10. It is reported that no significant changes are noted in range of motion, strength, or functional scores as evidenced by objective measures. On physical examination left shoulder active range of motion is abduction 121, external rotation 58, flexion 164, and internal rotation 71 degrees. Plan of care dated XX indicates that the patient has completed 28 physical therapy visits to date. Current pain level is 2/10. The patient has returned to working. On physical examination left shoulder range of motion is abduction 147, ER 72, flexion 168 degrees. Strength is +3/5 to +4/5 in the shoulder. Initial request for ERMI shoulder flexionator, 30 day rental for use of left side was non-certified on XX noting that the patient is status post left rotator cuff repair and has completed at least 23 post-operative physical therapy visits to date. Current evidence based guidelines note that flexionators are under study for adhesive capsulitis. No high quality evidence is yet available. While this device cannot yet be broadly recommended, it is an alternative option in conjunction with continued physical therapy if six weeks of physical therapy alone has been clearly unsuccessful in adequately correcting range of motion limitations secondary to refractory adhesive capsulitis, otherwise needing manipulation and/or adhesiolysis. In this case, the submitted records fail to establish the presence of adhesive capsulitis. It is unclear if the patient would otherwise need manipulation and/or adhesiolysis. The denial was upheld on appeal dated XX noting that Letter dated XX indicates that the device was ordered to help with the left shoulder to correct and get range of motion functional. The patient has not met range of motion goals. The patient has completed 27 physical therapy visits to date. There

is insufficient information to support a change in determination, and the previous non-certification is upheld. There are no serial physical therapy records submitted for review documenting the patient's progression with range of motion.

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

The request for ERMI shoulder flexionator, 30 day rental for use of left side is not medically necessary and the two previous denials are upheld. The submitted clinical records indicate that the patient is status post left shoulder arthroscopic rotator cuff repair and subacromial decompression on XX followed by a course of postoperative physical therapy. The Official Disability Guidelines note that the requested device is under study for adhesive capsulitis as no high-quality evidence (RCT) is yet available. The Official Disability Guidelines state that while this device cannot yet be broadly recommended, it is an alternative option in conjunction with continued physical therapy if 6 weeks of PT alone has been clearly unsuccessful in adequately correcting range of motion limitations secondary to refractory adhesive capsulitis, otherwise needing manipulation and/or adhesiolysis. The submitted clinical records fail to establish that in this case, without this device, this patient would require manipulation under anesthesia or adhesiolysis. Therefore, recommend non-certification.

IRO REVIEWER REPORT TEMPLATE -WC

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**

X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**

☐ **MILLIMAN CARE GUIDELINES**

X 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)**

Official Disability Guidelines Treatment Index, 23nd edition online, 2018-Shoulder Chapter updated 05/09/18

Flexionators (extensionators)
Under study for adhesive capsulitis.

See the Knee Chapter for more information and references

No high-quality evidence (RCT) is yet available. A retrospective study of frozen shoulder patients treated with the ERMI Shoulder Flexionater found no differences between groups with either low/moderate vs. high irritability in either external rotation or abduction (abduction improved from 52% to 85% for all over 15 months), but there was small sample size and no control group to compare with the natural history of the disease. (Dempsey, 2011) According to other studies, outcomes from regular PT and the natural history of adhesive capsulitis are about as good. (Dudkiewicz, 2004) (Guler-Uysal, 2004) (Pajareya, 2004) An ERMI funded retrospective analysis comparing 42 Flexionator postoperative adhesive capsulitis patients who plateaued during therapy vs. only 18 who did not plateau (PT only), showed similar final elevation and slightly better rotation with device use. (Wolin, 2016) Study limitations included lack of randomization, a meaningful control group, and small sample size.

While this device cannot yet be broadly recommended, it is an alternative option in conjunction with continued physical therapy if 6 weeks of PT alone has been clearly unsuccessful in adequately correcting range of motion limitations secondary to refractory adhesive capsulitis, otherwise needing manipulation and/or adhesiolysis. In this situation, it could be considered on a case-by-case basis for an initial 4-week home rental in conjunction with physical therapy as an alternative to more invasive (and costly) surgical procedures. If the patient subsequently experiences well documented gains in motion, then additional approval for a maximum of 4 additional weeks could also be reasonably considered.

Group health guidelines: 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 the use of PASS for the treatment of joint stiffness or contractures or to determine whether the use of these devices results in outcomes comparable to those achieved with established rehabilitation methods. (XX, 2015) The use of static progressive (SP) stretch splint and PASS devices for the treatment of joint contractures of the extremities alone or combined with standard physical therapy are unproven and not medically necessary. Clinical evidence is not sufficient to demonstrate that use of SP or PASS devices is a safe or effective treatment option. Studies are limited to small sample sizes. (XX, 2016) PASS devices are considered investigational and not medically necessary. (XX, 2015) Aetna considers PASS devices experimental and investigational because of insufficient scientific evidence of the effectiveness of these devices. (XX 2016)

Other guidelines, workers' comp: The ERMI Flexionator and Extensionater are not covered by workers' compensation in the State of Washington due to the absence of published literature showing safety and effectiveness. (Washington, 2016)