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Date notice sent to all parties: 01/12/18 (AMENDED 01/24/18)

IRO CASE #: XXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

ERMI Shoulder Flexinator Device

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

Board Certified in Orthopedic Surgery
Fellow of the American Academy of Orthopedic Surgeons
Fellow of the American Association of Orthopedic Surgeons
Diplomate of the American Board of Orthopedic Surgery

REVIEW OUTCOME:

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

☐ Upheld (Agree)

X Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

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

ERMI Shoulder Flexinator Device – Overturned

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient underwent examination/manipulation under anesthesia, diagnostic arthroscopy with arthroscopic capsular release (Limited glenohumeral debridement), and mini open rotator cuff repair of the left shoulder on XXXX by XXXX. The postoperative diagnoses were status post left shoulder anterior dislocation, rotator cuff tear, and adhesive capsulitis. The patient was then evaluated in therapy on XXXX. Flexion was 90 degrees, external rotation was 0 degrees, and internal rotation was 30 degrees. Therapy was recommended 3 times a week for 4 weeks. On XXXX, XXXX reevaluated the

patient. XXXX had been making progress and XXXX had marked limitation of range of motion on exam. Strength was limited due to pain. Since XXXX was still pretty tight, more aggressive therapy was recommended. Based on a therapy note on XXXX, XXXX had no new changes and reported left shoulder tightness. Passive external rotation was 35 degrees and it was felt XXXX could benefit from an ERMI ER device to increase XXXX range of motion. On XXXX, 12 additional sessions of therapy were approved and on XXXX, XXXX wrote a prescription for an ERMI Shoulder Flexinator Device. On XXXX, ERMI submitted a request for a 30 day authorization for the ERMI Shoulder Flexinator Device. On XXXX, it was noted XXXX passive range of motion was improving with flexion, but external rotation remained stiff. Passive, internal rotation was 60 degrees, flexion was 155 degrees, and external rotation was 45 degrees. Aggressive manual stretching would be continued. On XXXX, XXXX provided a denial for the requested left shoulder Flexinator. On XXXX, the patient followed-up with XXXX. It was noted the patient did not res XXXX to aggressive postoperative therapy and at XXXX last 2 visits, XXXX had marked limitation of motion. . XXXX recommended moving forward with MUA with arthroscopic evaluation, lysis of adhesions, and revision subacromial bursectomy in an effort to improve XXXX motion. On XXXX, another prescription was submitted for 30 days of use of the ERMI Shoulder Flexinator Device. On XXXX, ERMI submitted another preauthorization request for the device, which XXXX provided another denial for on XXXX.

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

The patient is a XX-year-old XXXX who was reported to have sustained a left shoulder dislocation as a result of a XXXX. It would appear that XXXX recovery was complicated by the development of adhesive capsulitis superimposed upon a rotator cuff tear. XXXX subsequently underwent a manipulation of the left shoulder under anesthesia followed by an arthroscopic debridement and mini open rotator cuff repair on XXXX by XXXX as noted above. The patient's physical therapy was initially delayed to allow healing of the rotator cuff repair. XXXX subsequently began a physical therapy rehabilitation program to regain motion, but had significant decreased motion as documented in the medical records reviewed. XXXX had subsequently made some improvement, but then appeared to plateau and subsequently decline. XXXX has subsequently recommended repeat surgical release and the use of the device following the second surgical procedure.

The Official Disability Guidelines (ODG) evidence based decision support notes that flexionators and extensionators are under study for adhesive capsulitis. No high quality randomized clinical trial is yet available. A retrospective study of frozen shoulder patients treated with the ERMI Shoulder Flexionator found no difference between groups with either low/moderate versus high irritability in either external rotation or abduction (abduction improved from 52% to 85% for all over fifteen months), but there was a small sample size and no control group to compare with the natural history of disease. (Dempsey 2011) According to other studies, outcomes from regular physical therapy and the natural history of adhesive capsulitis are about as good. (Dudkiewicz 2004) (Guler-Uysal 2004) (Pajarey 2004) An ERMI funded retrospective analysis comparing 42 flexionator postoperative adhesive capsulitis patients who plateaued during therapy versus only eighteen who did not plateau with physical therapy only showed similar final elevation and slightly better rotation with device use. (Wolin 2016) Study limitations include 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 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 situation, it could be considered on a case-by-case

basis for an initial four week home rental in conjunction with physical therapy as an alternative to more invasive and costly surgical procedures. It should be noted in this case that the surgeon is now considering a repeat surgical procedure and use of the device postoperatively. The patient has clearly undergone documented physical therapy preoperatively, as well as postoperatively following the initial surgical procedure. The patient still has significant motion limitations, as documented in the most recent notes by XXXX. Therefore, it is my opinion that the ERMI Shoulder Flexionator device for the left shoulder is medically necessary, reasonably related, and supported by the evidence based ODG and the previous adverse determinations should be overturned at this time.

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)**