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DATE: October 27, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

ERMI Flexionater Rental for 30 days E1399

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

The reviewer is certified by the American Board of Orthopedic Surgery with over 43 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.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who injured her left shoulder when she fell while working on XX/XX/XX.

xxxx: The claimant was evaluated for left anterior shoulder pain. She was diagnosed with closed dislocation humerus, anterior, left. The plan was for rest, shoulder exercises, sling, no heavy lifting, and physical therapy.

xxxx: The claimant was evaluated for complaints of continued sharp, stabbing pain in the anterolateral shoulder with certain motions, which was not getting any better. Exam showed positive impingement and pain with stressing the rotator cuff. An MRI showed a small full-thickness supraspinatus tear and impingement. She was given a steroid injection.

xxxxx: The claimant was evaluated for continued pain with lifting and reaching and pain with sleeping that was not getting any better. It was noted that a shoulder injection relieved the pain. The plan was to proceed with rotator cuff repair.

xxxx: Operative report. POSTOPERATIVE DIAGNOSIS: Left shoulder impingement syndrome, full-thickness supraspinatus tear. PROCEDURES PERFORMED: Examination under anesthesia, arthroscopy, left shoulder, subacromial decompression, and arthroscopic rotator cuff repair.

xxxx: The claimant was evaluated postoperatively. It was noted that her pain was improved. Her current pain rating was 4-9/10. The pain was located laterally and radiated into the upper arm, worse with activities. Her medications included Norco 10/325 mg 1 to 2 q. 4 to 6 hrs. p.r.n. pain. On exam of the left shoulder, there was normal inspection and palpation; stable; incisional tenderness; no swelling; and no erythema. Incisions were well healed. She had full

sensation to light touch in the median, radial, and ulnar nerve distributions. 2+ radial pulse. The plan was for activities as tolerated, exercises, and physical therapy.

xxxx: A daily progress note indicated that it was the 5th therapy visit. The claimant rated her pain as 5/10. She underwent therapeutic exercise and manual therapy. Her response to treatment included increased flexibility, increased endurance, increased range of motion, and increased exercise tolerance. She had stiffness prior to PROM; pain increased with PROM.

xxxx: UR. RATIONALE: There is no evidence in the submitted records that the patient is diagnosed with adhesive capsulitis supporting treatment with a flexionator. Nevertheless, there is insufficient evidence demonstrating the safety, efficacy, and long-term outcomes of their use for the treatment of joint stiffness or contractures, and there is no evidence that these devices are comparable to established treatment methods.

xxxx: The claimant was evaluated. It was noted that she felt her left shoulder was improving. Her medications included Norco 10/325 mg 1 to 2 q. 4 to 6 hrs. p.r.n. pain. No exam was documented. She was to continue with physical therapy.

xxxx: The claimant was evaluated. Her chief complaint was that of RIGHT shoulder pain located anteriorly and laterally that was mild and worsened with activities and during and after physical therapy. She felt that range of motion was normal. She denied any LEFT shoulder symptoms. Her medications included Norco 10/325 mg. On exam, there was no clubbing, cyanosis, edema, or deformity noted with normal full range of motion of all joints except the left shoulder. Neurological exam was intact with intact sensation and normal reflexes, coordination, muscle strength and tone. Left shoulder inspection and palpation were normal; stable; no tenderness; no swelling; no erythema; 130 of forward flexion; 85 degrees of external rotation, internal rotation to L5; full sensation to light touch in the median, radial, and ulnar nerve distribution; 2+ radial pulses. The plan was for activities as tolerated, exercises, and physical therapy 3 times per week for 4 weeks.

xxxx: UR. It was noted that a letter of medical necessity was submitted dated xxxx which indicated that the claimant had been using the ERMI shoulder Flexionator for the past month and had improved range of motion from 9 to 50 degrees on external rotation and 65 to 140 degrees on abduction. RATIONALE: It is not clear whether the improvement in range of motion was directly related to the use of the flexionator since she was concurrently doing physical therapy. Moreover, there was no comprehensive clinical evaluation to show evidence that the patient has adhesive capsulitis to warrant treatment with a flexionator. Nevertheless, there is insufficient evidence demonstrating the safety, efficacy, and long-term outcomes of their use for the treatment of joint stiffness or contractures, and there is no evidence that these devices are comparable to established treatment methods.

xxxx: Daily progress note indicates that it was visit No. 31. She reported no pain currently. Her short-term goals were to increase left shoulder flexion range of motion from 150 degrees to 160 degrees; increase left shoulder abduction range of motion from 143 degrees to 150 degrees; increase left shoulder IR range of motion from 65 degrees to 72 degrees; and increase left shoulder strength to 5/5. Long-term goals were increase left shoulder flexion to 170 degrees; abduction to 160 degrees; IR range of motion to 80 degrees; maximize left shoulder strength; and do all ADLs without difficulty. She underwent therapeutic exercise, exercise instruction, and manual therapy. Remaining impairment requiring continued treatment included decreased flexibility, decreased range of motion, decreased strength, pain, increased difficulty with ADLs, and increased muscle tension. Comments: IR and abduction discomfort and tightness, patient unable to put her hair into a ponytail, patient using L UE for work activities, improving range of motion and strength. The plan was to continue with plan of care.

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

The previous adverse decisions are upheld. As noted in the ODG regarding the ERMI for capsulitis (shoulder), there is no evidence that its use is better than traditional treatment with physical therapy and home exercises. Additionally,

there is no documentation submitted that would indicate the claimant has capsulitis. Therefore, the request for ERMI Flexionater Rental for 30 days E1399 is not medically necessary.

ODG:

Flexionators (extensionators)	Under study for adhesive capsulitis. No high quality evidence is yet available. A study of frozen shoulder patients treated with the ERMI Shoulder Flexionater found there were no differences between the groups with either low or moderate/high irritability in either external rotation or abduction (glenohumeral abduction went from about 52% to 85% in both groups over a 15-month period), but there was no control group to compare these outcomes to 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) See the Knee Chapter for more information and references.
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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
- 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)