

Icon Medical Solutions, Inc.

11815 CR 452
Lindale, TX 75771
P 903.749.4272
F 888.663.6614

DATE: May 6, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

30 day rental of the ERMI shoulder Flexionater 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 Physical Medicine and Rehabilitation with over 16 years of experience.

REVIEW OUTCOME:

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

Overturned (Disagree)

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 male who sustained a right rotator cuff injury while working on xx/xx/xx.

05/20/14: MRI Right Shoulder W/O Contrast report. IMPRESSION: Moderate-sized full-thickness tear of the supraspinatus tendon of 3 cm in longitudinal dimension. High-grade partial thickness tearing of the superior half of the subscapularis tendon with marked attenuation or disruption of the long head of the biceps tendon at the top of the bicipital groove. Linear tearing of the superior labrum and superior half of the anterior labrum.

11/20/14: MRI Right Shoulder W/O Contrast report. IMPRESSION: Rotator cuff repair. No fluid-filled rotator cuff tear is evident. Mild articular fraying of the supraspinatus distal insertion posteriorly would be possible. Tendinosis, low-grade partial longitudinal tear, slight medial subluxation, and mild tenosynovitis of the proximal long biceps tendon. Thickening and intermediate signal of the glenohumeral joint capsule anteriorly compatible with the provided history of adhesive capsulitis. No paralabral cyst or definite labral tear is seen.

11/21/14: The claimant was evaluated. He had right shoulder pain that had not gotten better after surgery. He had marked restriction of motion, and he felt when he tried to move it beyond 90 degrees, it hurt and was tight. On exam, he had marked limitation of motion of the right upper extremity and good function of his hand and elbow. Assessment was adhesive capsulitis and biceps tendinitis. felt that an intra-articular injection and a course of therapy would help him to improve. He was given a right shoulder glenohumeral joint injection of ketorolac tromethamine 15 mg.

11/24/14: The claimant began rehab to the right upper extremity (3 times per week for 4 weeks).

12/05/14: The claimant was evaluated. It was noted that he had been using tramadol as needed and naproxen with good effects. He had surgery on 07/02/14 and had done a trail of physical therapy, which he stated did have some improvement. He reported continued pain and decreased range of motion. VAS 5/10. On exam, there was tenderness to palpation over the right shoulder. Speed test was positive. Yergason sign was positive. Range of motion was severely decreased in abduction. Flexion and extension showed pain against resistance and end range. Dermatomes, myotomes, and flexor zones were within normal limits. Assessment was right shoulder pain status post injury, surgery 07/02/14 and muscle spasms. The plan was for activity to tolerance, D-WIC up to date, tramadol (received prescription for tramadol 50 mg t.i.d. #90), and return to clinic in 1 month.

02/10/15: The claimant was evaluated. He stated that he was in a lot of pain and on some days took up to 300 mg of tramadol. On exam, the joints showed tenderness. There was no clubbing or edema. Peripheral pulses were intact. Range of motion for right shoulder abduction was reduced, 79 degrees; right shoulder adduction was reduced, 27 degrees; right shoulder extension was reduced, 31 degrees; right shoulder external rotation was reduced, 39 degrees; right shoulder flexion was reduced, 105 degrees; right shoulder internal rotation was reduced, 26 degrees. Plan was refer to orthopedic surgeon to evaluate and treat, a prescription was given for tramadol 50 mg 1-2 b.i.d. #120, refer to pain management, and to PCP for hypertension.

02/27/15: Letter. "My patient sustained a right rotator cuff tear on xx/xx/xx and subsequently underwent a rotator cuff repair. He was approved for this procedure due to his inability to regain right shoulder range of motion post his original work related injury and treatment on 3/22/14. Thus far has diligently attended physical therapy for over three months and has made minimal progress. Given the patient's continued failure of conservative treatment and history of arthrofibrosis, I am prescribing the ERMI Shoulder Flexionater for 30 days to use in conjunction with physical therapy. Despite rigorous physical therapy and other routine treatment options for his shoulder, is limited to 36 degrees of external rotation, 33 degrees of internal rotation, and 34 degrees of abduction. These ranges of motion were recorded on 2/25/15. These ranges are far short of his treatment goals of 90 degrees of external rotation, 70 degrees of internal rotation and 180

degrees of abduction. Patients with less than 90 degrees of external rotation motion may require additional surgical procedures to help regain the motion necessary to perform activities of daily living and allow a timely return to work. I ordered the ERMI Shoulder Flexionater to help regain range of motion and avoid additional surgery. In my clinical experience, patients that I have treated with the Shoulder Flexionater demonstrated marked, lasting motion gains after relatively short durations of use. I believe that this high intensity device is the only conservative treatment option for to help avoid an additional surgery and that the use of the Shoulder Flexionater device is reasonable and medically necessary. In conclusion, this device is medically necessary to get back to work and avoid further costly treatment including future range of motion restoring surgeries.

03/04/15: The claimant was evaluated. He complained of right shoulder pain. On exam, extremity joints showed tenderness to the right shoulder. Flexion of the right shoulder was 90 degrees. He was referred to for evaluation and possible injection. He was given a prescription for tramadol 50 mg 1-2 b.i.d. #120.

03/18/15: The claimant was evaluated. He reported that his pain level was approximately the same as it was versus his preoperative status. It was noted that his treatment post surgery included pain medications as well as an exercise machine plus the immediate postop physical therapy. He reported that the most bothersome thing was painful elevation of the right arm. He underwent shoulder injection in November but it did not provide him with any significant relief. Right shoulder x-rays done in office on this date demonstrated an 8.1 mm acromiohumeral interval with mild sclerotic and proliferative bony change noted about the greater tuberosity. There was questionable minimal proximal migration of the humeral head and a type II acromion. There was no evidence of fracture or dislocation. On exam, range of motion appeared to be intact in all planes. He had considerable pain with attempted elevation of the arm. "With some difficulty, I believe I am able to achieve a full elevation of the arm in a passive mode." Sensory function was intact. Negative Popeye sign. No deformity or atrophy about the shoulder girdle. Impingement maneuver was markedly positive. Speed's and Yergason's tests were mildly positive. He had positive O'Brien's test. A diagnostic subacromial Marcaine injection was carried out. After 10 minutes post injection, exam suggested a significant relief of his discomfort. His impingement maneuver was far less positive. Range of motion in general was more comfortable for him. Impression was persistent impingement syndrome right shoulder. The recommendation was for diagnostic arthroscopy of the shoulder with arthroscopic acromioplasty.

03/19/15: UR. RATIONALE: The request for DME Shoulder Flexionater Daily Rental x 30 days, total price \$3,339.00 for dates 02/27/2015 through 03/28/2015 is not medically necessary. There is a note from September 2014 that stated there was reduced motion. There was an MRI in May 2014 that showed rotator cuff tear. There is no updated exam, no operative note, and no clinical rationale for the DME. The request does not meet evidence based guidelines.

03/25/15: Letter. “range of motion to the right shoulder is at 74 degrees of abduction external rotation 36 degrees with a goal of 90 and internal rotation 33 degrees with a goal of 70.” “The Shoulder Flexionater was ordered to help him to improve his range of motion by providing him with the greatest opportunity for successful clinical and functional outcomes. Without the use of the ERMI device, the likelihood for additional procedures will be much greater.” “The Shoulder Flexionater is a high intensity mechanical therapy device used in the patient’s home as an adjunct to physical therapy to help improve motion and is used for one hour per day; however, this device is not to be confused with a CPM machine. CPM machines slowly move the joint through the available range of motion. These machines provide very low loads to the joint and only hold the joint at the end range of motion for a brief moment.” “The Flexionater provides nearly six times the torque as a CPM.”

03/30/15: UR. The medical information does not establish the medical necessity for the device requested. The injured worker is 1 year post injury with a diagnosis of adhesive capsulitis and he has failed physical therapy treatment to improve motion. Evidence based studies do not support the use of a Flexionater and passive therapy is not supported beyond the acute to subacute phase of injury. Thus the request is not supported by the medical treatment guidelines.

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

The previous adverse decisions are overturned. For the diagnosis and post-operative imaging study confirmation of adhesive capsulitis and given clinical documentation of minimal change in shoulder range of motion From November 2014 to February 2015 despite post-operative Physical therapy and steroid injection during that time, the request for 30 day rental of the ERMI shoulder Flexionater E1399 meets ODG criteria and is 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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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)**