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An Independent Review Organization
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Description of the service or services in dispute:
End range motion improvement (ERMI) Shoulder Flexionater range of motion device

Description of the qualifications for each physician or other health care provider who reviewed the decision: Board Certified Orthopedic Surgeon

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

- ☐ Overturned (Disagree)
- ☑ Upheld (Agree)
- ☐ Partially Overturned (Agree in part / Disagree in part)

Patient Clinical History (Summary)
XXXX. On XXXX, XXXX was XXXX and felt a sensation in the left shoulder. XXXX was diagnosed with sprain of left rotator cuff capsule, subsequent encounter (S43.422D) and stiffness of the left shoulder, not elsewhere classified (M25.612).

On XXXX, XXXX was seen in an orthopedic follow-up by XXXX following left shoulder arthroscopic subacromial decompression and distal clavicle resection. XXXX reported discomfort with overhead activities. XXXX had some improvement with physical therapy. XXXX had not received the flexionater chair at the time. XXXX complained of pain with abduction maneuvers. On examination, there was mild tenderness along the acromioclavicular joint and the anterior acromion. There was mild discomfort with extreme overhead motion and abduction. The left shoulder demonstrated 165 degrees of abduction with pain, 170 degrees of elevation, 35 degrees of external rotation, 45 degrees of extension and internal rotation to L4.

An MRI report dated XXXX was documented by XXXX in a designated doctor examination done on XXXX. The study revealed moderate acromioclavicular arthrosis with distal clavicle osteolysis. There was high-grade sprain of the acromioclavicular ligaments without discrete tear. Acromioclavicular alignment was preserved and the coracoclavicular ligament was intact. No other internal derangements of the shoulder were noted. (XXXX, page 16)

The treatment to date included left shoulder arthroscopic subacromial decompression, distal clavicle resection, synovectomy and insertion of an On-Q pain pump into the left shoulder on XXXX; 32 sessions of physical therapy; medications (XXXX); and injections (XXXX).

Per a utilization review decision letter dated XXXX, the request for 30 days rental of End Range Motion Improvement (ERMI) for the left shoulder flexionater between XXXX was denied. Rationale: “Per evidence-based guidelines, flexionaters are still under study for adhesive capsulitis and there is no high-quality evidence available yet. The patient had a left shoulder surgery on XXXX. XXXX completed 32 sessions of physical therapy. XXXX reported improvement with formal physical therapy. XXXX continued to have limitation of motion in rotation and had some discomfort with overhead activities. The provider recommended the use of flexionater chair to regain full external rotation and formal physical

therapy to continue on additional motion and strengthening of the shoulder. However, the guideline states that 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. In addition, other studies revealed outcomes from regular physical therapy and the natural history of adhesive capsulitis are about as good. Peer to peer conducted with peer designee, XXXX and case discussed. XXXX confirms the patient underwent a left shoulder examination under anesthesia, arthroscopic subacromial decompression, synovectomy, bursectomy, distal clavicle resection and insertion of a pain pump on XXXX. XXXX has completed 32 sessions of physical therapy with reported improvement with formal physical therapy. XXXX has continued limitation of motion. Based on the information provided, guidelines reviewed and peer discussion, the request is not medically supported at this time and thus, non-certified."

Per a utilization review decision letter dated XXXX, the request of 30 days rental of End Range Motion Improvement (ERMI) for the left shoulder flexionater between XXXX was denied. Rationale: "Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced below, this request is non-certified. There was no evidence indicating that this request is to be used in conjunction with continued physical therapy."

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

The ODG states that the use of flexionators is under study for adhesive capsulitis and notes that while the device cannot yet be broadly recommended, it is an alternative option in conjunction with continued physical therapy if six weeks of physical therapy alone have been clearly unsuccessful or inadequate in correcting range of motion limitations secondary to refractory adhesive capsulitis. The provided documentation indicates that a left shoulder arthroscopy, subacromial decompression, synovectomy, bursectomy, and distal clavicle resection were performed on XXXX. There is evidence that 32 visits of physical therapy have been completed with improvements, but some persistent deficits remain. The most recent provided clinical progress note is from XXXX and reveals abduction of 165°, forward elevation of 170°, external rotation of 45°, and internal rotation to L4. The clinician notes that the injured worker has improved with physical therapy but continues to have some limitations of motion, and there is a recommendation for a flexionator chair to work on abduction. A prescription for an ERMI flexionator from XXXX states that the device is medically necessary to help with range of motion deficits indicative of adhesive capsulitis. There is no indication that the device is to be used in conjunction with continued physical therapy, nor is there any indication why the device is necessary when the most recent documented shoulder abduction is 165°. Based on the provided documentation, the recommendation is to uphold the two previous denials. Given the documentation available, the requested service(s) is considered not medically necessary.

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

- ☐ ACOEM-America College of Occupational and Environmental Medicine
- ☐ AHRQ-Agency for Healthcare Research and Quality Guidelines
- ☐ DWC-Division of Workers Compensation Policies and Guidelines
- ☐ European Guidelines for Management of Chronic Low Back Pain
- ☐ Interqual Criteria
- ☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards
- ☐ Mercy Center Consensus Conference Guidelines
- ☐ Milliman Care Guidelines

☑ ODG-Official Disability Guidelines and Treatment Guidelines
Shoulder Chapter ***Flexionators (extensionators)*** - *Under study for adhesive capsulitis.*

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.

☐ Pressley Reed, the Medical Disability Advisor
☐ Texas Guidelines for Chiropractic Quality Assurance and 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)

Appeal Information

You have the right to appeal this IRO decision by requesting a Texas Department of Insurance, Division of Workers' Compensation (Division) Contested Case Hearing (CCH). A Division CCH can be requested by filing a written appeal with the Division's Chief Clerk no later than 20 days after the date the IRO decision is sent to the appealing party and must be filed in the form and manner required by the Division.

Request for or a Division CCH must be in writing and sent to:
Chief Clerk of Proceedings Texas Department of Insurance
Division of Workers' Compensation P. O. Box 17787
Austin, Texas, 78744

For questions regarding the appeals process, please contact the Chief Clerk of Proceedings at 512-804-4075 or 512- 804-4010. You may also contact the Division Field Office nearest you at 1-800-252-7031.