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IRO Certificate #4599

DATE OF REVIEW: 6/01/15

IRO CASE NO.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

ERMI Shoulder Flexionater x 30 days (3/27/15-4/25/15) CPT: E1399

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

Physician Board Certified in Physical Medicine & Rehabilitation

REVIEW OUTCOME

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

Upheld	(Agree) <input checked="" type="checkbox"/>
Overtured	(Disagree)
Partially Overtured	(Agree in part/Disagree in part)

PATIENT CLINICAL HISTORY SUMMARY

is a male who underwent an arthroscopic rotator cuff repair (subscapularis, supraspinatus) and subacromial decompression, distal clavicle resection, SLAP repair, and lysis of adhesions on 1/20/15. He sustained a work related injury which did not respond to conservative non-operative treatment, which resulted in the surgery. Physical therapy notes from 1/28/15 mention that the "extensionater" (likely typo for flexionater) is "helpful to stretch his shoulder. No resting pain. Shoulder relaxes after hold stretch a short time, then movement improves". PROM documented on 1/28/15: abd 95, forward flex 145, ext 35, ext rotation at 90 degrees of abduction 60, and internal rotation at 90 degrees of abduction 35, 45 degrees abd IR 65 degrees, and ER 60 degrees IR behind back. Note from 2/21/15 notes prescription for flexionater, shoulder. Per review letter dated 5/14/15, patient's shoulder ROM improved to ext rotation 60 and abduction 95 degrees which was measured on 3/30/15 after use of the flexionater.

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

**Opinion: I agree with the benefit company's decision to deny the requested service.**

Rationale: This review pertains to the use of ERMI Shoulder Flexionater for 30 days post-op period. Per ODG, the Flexionater is under study for adhesive capsulitis, showed no differences between high irritability vs low or moderate irritability of the shoulder but no control group. (Dempsey 2011-same article quoted on the SPEC sheet of the Flexionater)

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION (continuation)

It is expected that in normal post-op course, including physical therapy and home exercise, that range of motion would improve. There are no controlled studies that show benefit of use of Flexionater over the use of no device. Until that type of study becomes available, it is difficult to support the use of this device. For all the reasons stated, I agree with the company's decision to deny the requested service.

**DESCRIPTION AND SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION**

ACOEM-AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL  
MEDICINE UM KNOWLEDGE BASE

AHCPR-AGENCY FOR HEALTH CARE 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 & EXPERTISE IN ACCORDANCE WITH  
ACCEPTED MEDICAL STANDARDS X**

MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

MILLIMAN CARE GUIDELINES

**ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES X**

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 X**  
(PROVIDE DESCRIPTION)

\* Dempsey AL, Mills T, Karsch RM, Branch TP, "Maxmizing Total End Range Time is Safe & Effective for the Conservative Treatment of Frozen Shoulder Patients", American Journal of Physical Medicine & Rehabilitation, 2011, 10.1097/PHM.0b013e318214ed0d

\* ERMI Shoulder Flexionater Specifications Sheet (taken from the same source above)

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES  
(PROVIDE DESCRIPTION)