IMED, INC.

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Notice of Independent Review Decision

[Date notice sent to all parties]:

8/7/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: ERMI shoulder flexionator 5/10/2015-6/8/2015

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

REVIEW OUTCOME:

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

X 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]:

Complaint - This gentleman was injured while working. The medical records that have been presented for review in this case show that he fell and injured his right shoulder and his left knee.

evaluated the claimant and prescribed conservative care. He had physical therapy, injections in the right shoulder, and an MRI reported partial tears in the rotator cuff. performed surgery for debridement of the synovitis and repair of the rotator cuff. The gentleman had additional physical therapy and regained most of his range of motion. The doctor has now prescribed the use of an ERMI flexionater device for home uses to increase the range of motion. The doctor uses as rationale the

finding that range of motion had improved while using the device and while participating in physical therapy.

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

According to the ODG recommendations, criteria for the use of a flexonator for shoulder dysfunctiona are under study. According to ODG, there are no high-quality studies that provide any evidence of superiority of this device over standard physical therapy and home exercise. The existing study utilized a series of patients who used the device for 15 months and improved range of motion. However, there was no control group, and the results could not be compared with the natural history of the disease. According to other studies, the results from regular therapy and the natural history of adhesive capsulitis are about the same.

presents a very well-reasoned rationale for consideration of the utilization of this device, stating that range of motion had improved while utilizing the device. However, according to peer-reviewed research, there is no evidence to demonstrate superiority of the device over routine conservative care.

Therefore, the request for certification for this device from 05/10/15 to 06/18/15 is not certified for lack of quality evidence of efficacy and for lack of compliance with ODG recommendations.

IRO REVIEWER REPORT TEMPLATE -WC

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

X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS