mcmc
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Notice of Independent Review Decision

DATE OF REVIEW:
03/21/2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
shoulder device to restore range of motion (ROM).

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
Board Certified Physical Medicine and Rehabilitation Physician.

REVIEW OUTCOME
Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: **Upheld**

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.
The shoulder device to restore range of motion is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW
- MCMC: Case Report dated 03/05/08
- MCMC Referral dated 03/05/08
- DWC: Notice of Assignment of Independent Review Organization dated 03/05/08
- DWC: Confirmation Of Receipt Of A Request For A Review dated 03/04/08
- LHL009: Request For A Review By An Independent Review Organization dated 03/04/08
- Letter dated 03/04/08 from, DO
- Letter dated 02/19/08 from
- Statement of Medical and/or Prescription signed 02/18/08, 01/29/08
- Group: Follow Up Note dated 02/15/08 from, M.D.
- Letter dated 02/04/08 from, M.D.
- Fax cover sheet dated 01/31/08 with Comment from
- PT: Transcription note dated 01/15/08
- PT: Letter dated 01/15/08
- DME Preauthorization Request dated 01/15/08
- Group: Initial Report dated 12/21/07 from, M.D.
- Hand Therapy Prescription dated 12/21/07
- Research, Inc.: Memo dated 07/10/07
- U.S. Food and Drug Administration: Article entitled, “Device Listing Database” updated 07/06/07
- U.S. Food and Drug Administration: Article entitled, “Establishment Registration Database” updated 07/06/07

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- Letter dated 04/11/07 from, Director
- Letter dated 11/07/06
- Letter dated 08/09/06
- Testimonials for Devices dated 02/01/06 with attached Testimonials dated 11/20/98 through 11/17/06
- Form letter dated 05/24/06 from, M.D.
- Binded Biography Report dated 05/22/06 (poor copy)
- U.S. Food and Drug Administration: Title 21- Food and Drugs Chapter I updated 04/01/06
- M.D.: Letter dated 10/08/04
- Medical Centers: Undated Patient Referral
- Undated information on stimulators
- Undated Published Journal Articles on "Joint Active Systems and Static Progressive Stretch"
- Undated article with "Simulates Manual Stretch" at top (one page)
- Undated article entitled, "Only JAS"
- Undated article entitled, "Pennsylvania MCO Utilization of JAS Device"
- Undated article entitled, "Joint Active Systems Preliminary Data Overview" from, RN
- Palmetto GBA: Article entitled, "Joint Contracture Devices: New and Revised HCPCS Codes"
- Undated Department of Insurance Financial Institutions and Professional Registration
- Device Listing (date not legible)
- NOTE: Carrier did not supply ODG guidelines.

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured individual is a xx year-old male who has history of left shoulder dysfunction with an adhesive capsulitis and a work injury date of xx/xx/xx. According to a clinic note by, M.D. on 12/21/2007, the injured individual had a traumatic injury to the neck and left shoulder area with a frozen shoulder in which range of motion with external rotation was 10-20 degrees, internal rotation to the beltline area, and forward flexion of 70 degrees with a rigid endpoint. Physical therapy was recommended. Per clinic note by Dr. on 02/15/2008, the injured individual was undergoing a frozen shoulder therapy protocol with progressive bracing, but the specific outcome from that treatment was not clear. A shoulder device to restore range of motion is being requested. However, it is not clear why this device is required as opposed to conventional treatments including manipulation under anesthesia, physical therapy, and a daily home exercise program. Also the functional goals and treatment endpoints were not clearly outlined.

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

It is not clear why the Shoulder device is required as opposed to other conventional treatments for adhesive capsulitis including manipulation under anesthesia, physical therapy, and a daily home exercise program. Also, functional goals and treatment endpoints were not clearly outlined. The use of modalities such as the requested shoulder device is unproven as an effective treatment alternative for this type of shoulder condition. According to the ODG guidelines regarding adhesive capsulitis management, "For adhesive capsulitis, injection of corticosteroid combined with a simple home exercise program is effective in improving shoulder pain and disability in patients. Adding supervised

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physical therapy provides faster improvement in shoulder range of motion. When used alone, supervised physical therapy is of limited efficacy in the management of adhesive capsulitis. (Carette, 2003) Physical therapy following arthrographic joint distension for adhesive capsulitis provided no additional benefits in terms of pain, function, or quality of life, but resulted in sustained greater active range of shoulder movement and participant-perceived improvement up to six months. (Buchbinder, 2007) Physical modalities, such as massage, diathermy, cutaneous laser treatment, ultrasonography, transcutaneous electrical neurostimulation (TENS) units, and biofeedback are not supported by high quality medical studies, but they may be useful in the initial conservative treatment of acute shoulder symptoms, depending on the experience of local physical therapists available for referral." As a result, the requested JAS Shoulder device to restore range of motion is not medically necessary.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Official Disability Guidelines regarding Adhesive capsulitis management, "For adhesive capsulitis, injection of corticosteroid combined with a simple home exercise program is effective in improving shoulder pain and disability in patients. Adding supervised physical therapy provides faster improvement in shoulder range of motion. When used alone, supervised physical therapy is of limited efficacy in the management of adhesive capsulitis. (Carette, 2003) Physical therapy following arthrographic joint distension for adhesive capsulitis provided no additional benefits in terms of pain, function, or quality of life but resulted in sustained greater active range of shoulder movement and participant-perceived improvement up to 6 months. (Buchbinder, 2007) Physical modalities, such as massage, diathermy, cutaneous laser treatment, ultrasonography, transcutaneous electrical neurostimulation (TENS) units, and biofeedback are not supported by high quality medical studies, but they may be useful in the initial conservative treatment of acute shoulder symptoms, depending on the experience of local physical therapists available for referral."