

Notice of Independent Review Decision

DATE OF REVIEW: NOVEMBER 2, 2010 Amended November 4, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Rt hardware removal, humerus, possible ORIF w/bone graft, exchange nailing.
Rt shoulder arthroscopy w/ subacromial decompression, RCR outpatient.

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

This physician is Board Certified by American Board of Orthopedic Surgeons with 43 years of experience.

REVIEW OUTCOME

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

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

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

On May 4, 2010, M.D., an orthopedic surgeon evaluated the claimant. He has complaints of itching pain and hand swelling status post right humerus fracture that was splinted. Impression: Right humeral shaft fracture, spiral, extending toward head. Tuberosity appears intact.

On May 7, 2010, a C-arm Fluoroscopy was performed during ORIF right humeral fracture as interpreted by M.D.

On May 7, 2010, the claimant underwent surgical intervention of the right humerus as performed by M.D. Procedures: 1. Open reduction and internal fixation/intramedullary nailing right humeral shaft fracture. 2. Rotator cuff repair. 3. Complex multilayered closure. 4. Application of sling shot abduction pillow.

On May 13, 2010, the claimant was re-evaluated by M.D. He has no complaints post surgery.

On May 13, 2010, X-Rays of the right humerus were performed. Impression: The distal fragment continues to show lateral displacement with respect to the proximal fragment as interpreted by M.D.

On June 3, 2010, the claimant was re-evaluated by M.D. He is having shoulder and deltoid-type pain and his elbow is stiff. Impression: 1. Status post IMN, right humeral shaft fracture. 2. Backout proximal locking screw with shoulder pain. The claimant needs to do gentle range of motion with active and passive stretching and limit activities that irritate the deltoid to get enough callus formation to remove the proximal locking bolt.

On June 22, 2010, the claimant was re-evaluated by M.D. He is still having shoulder pain with a grinding type feeling. X-Rays did not show a whole lot of new bone formation at the fracture site. He was injected with Depo-Medrol and Lidocaine to give him temporary pain relief.

On July 6, 2010, the claimant was re-evaluated by M.D. He is having shoulder pain with any attempt at forward elevation or abduction. X-Rays showed good bone callus forming at the fracture site. The nail really slid and it is now very prominent in the subacromial space. The humerus needs to heal more before the hardware can be removed.

On July 6, 2010, X-Rays were taken of the right shoulder. Impression: Mild interval healing of humeral fracture as interpreted by M.D.

On August 2, 2010, X-Rays were taken of the right shoulder. Impression: Stable fracture proximal humeral shaft traversed by an intramedullary rod as interpreted by M.D.

On August 2, 2010, X-Rays were taken of the right humerus. Impression: Healing fracture as interpreted by M.D.

On August 3, 2010, the claimant was re-evaluated by M.D. He is having difficulty moving his right shoulder. Dr. recommended one more month of healing before hardware removal.

On September 1, 2010, X-Rays were taken of the right shoulder. Impression: A finding that may or may not be significant is protrusion of screw fixing the rod barely protruding through the cortex of the humeral head. The shoulder region is otherwise unremarkable as interpreted by M.D.

On September 1, 2010, X-Rays were taken of the right humerus. Impression: Further healing of the humerus shaft fracture with some fracture radiolucency still evident as interpreted by M.D.

On September 2, 2010, the claimant was re-evaluated by M.D. He has complaints of right shoulder pain, stiffness, catching, popping and weakness. Impression: 1. Long spiral diaphyseal-metaphyseal right humerus fracture, s/p IMN. 2. Hardware complication: proximal nail migration into subacromial space. 3. Rotator cuff perforation, secondary to the above. Dr. recommended right humeral IMN removal, possible exchange nailing with ORIF and bone graft, possible DSA, SAD, and RCR.

On September 29, 2010, M.D. an orthopedic surgeon, performed a utilization review on the claimant. Rational for Denial: There is no imaging documentation of a rotator cuff tear. Although he patient meets the criteria for removal of hardware, ORIF and exchange nailing, the evidence based guideline criteria for the associated SAD and RCR have not been met. Therefore, it is not certified.

On October 14, 2010, D.O., an orthopedic surgeon, performed a utilization review on the claimant Rational for Denial: The request for hardware removal is appropriate and medically necessary however the right shoulder arthroscopy with subacromial decompression and RCR is not recommended. There is no evidence that the patient has utilized conservative care such as physical therapy for the shoulder and the imaging study did not document a rotator cuff tear. Therefore, it is not certified.

PATIENT CLINICAL HISTORY:

On xx/xx/xx, the claimant sustained and injury to the right humerus when he stepped in a hole and fell on his face, hitting his right arm in the process.

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

The previous decisions are partially overturned. The removal of the intramedullary rod and locking screws is indicated because of pain and impingement in the subacromial space per x-ray evidence. Repair of rotator cuff defect caused by the protruding rod is indicated and should be done at the time of the removal of the intramedullary rod. There is no indication for subacromial decompression procedure based on the medical records provided. There is no evidence of non-union presented in the records that would indicate need for replacement of the intramedullary nail and bone grafting. The attending physician thinks there is a possibility of non-union. This should be diagnosed prior to removal of the rod and if present, ORIF with intramedullary rod and bone graft would be indicated.

Per the ODG:

Hardware Removal:

Not recommend the routine removal of hardware implanted for fracture fixation, except in the case of broken hardware or persistent pain, after ruling out other causes of pain such as infection and nonunion. Not recommended solely to protect against allergy, carcinogenesis, or metal detection. Although hardware removal is commonly done, it should not be considered a routine procedure. The decision to remove hardware has significant economic implications, including the costs of the procedure as well as possible work time lost for postoperative recovery, and implant removal may be challenging and lead to complications, such as neurovascular injury, refracture, or recurrence of deformity. Current literature does not support the routine removal of implants to protect against allergy, carcinogenesis, or metal detection. ([Busam, 2006](#)) Despite advances in metallurgy, fatigue failure of hardware is common when a fracture fails to heal. Revision procedures can be difficult, usually requiring removal of intact or broken hardware. ([Hak, 2008](#)) Following fracture healing, improvement in pain relief and function can be expected after removal of hardware in patients with persistent pain in the region of implanted hardware, after ruling out other causes of pain such as infection and nonunion. ([Minkowitz, 2007](#))

ODG Indications for Surgery □ -- Rotator cuff repair:

Criteria for rotator cuff repair with diagnosis of full thickness rotator cuff tear AND Cervical pathology and frozen shoulder syndrome have been ruled out:

- 1. Subjective Clinical Findings:** Shoulder pain and inability to elevate the arm; tenderness over the greater tuberosity is common in acute cases. PLUS
- 2. Objective Clinical Findings:** Patient may have weakness with abduction testing. May also demonstrate atrophy of shoulder musculature. Usually has full passive range of motion. PLUS

3. Imaging Clinical Findings: Conventional X-Rays, AP, and true lateral or axillary views. AND Gadolinium MRI, ultrasound, or arthrogram shows positive evidence of deficit in rotator cuff.

Criteria for rotator cuff repair OR anterior acromioplasty with diagnosis of partial thickness rotator cuff repair OR acromial impingement syndrome (80% of these patients will get better without surgery.)

1. Conservative Care: Recommend 3 to 6 months: Three months is adequate if treatment has been continuous, six months if treatment has been intermittent. Treatment must be directed toward gaining full ROM, which requires both stretching and strengthening to balance the musculature. PLUS

2. Subjective Clinical Findings: Pain with active arc motion 90 to 130 degrees. AND Pain at night (Tenderness over the greater tuberosity is common in acute cases.) PLUS

3. Objective Clinical Findings: Weak or absent abduction; may also demonstrate atrophy. AND Tenderness over rotator cuff or anterior acromial area. AND Positive impingement sign and temporary relief of pain with anesthetic injection (diagnostic injection test). PLUS

4. Imaging Clinical Findings: Conventional X-Rays, AP, and true lateral or axillary view. AND Gadolinium MRI, ultrasound, or arthrogram shows positive evidence of deficit in rotator cuff.

ODG Indications for Surgery -- Acromioplasty:

Criteria for anterior acromioplasty with diagnosis of acromial impingement syndrome (80% of these patients will get better without surgery.)

1. Conservative Care: Recommend 3 to 6 months: Three months is adequate if treatment has been continuous, six months if treatment has been intermittent. Treatment must be directed toward gaining full ROM, which requires both stretching and strengthening to balance the musculature. PLUS

2. Subjective Clinical Findings: Pain with active arc motion 90 to 130 degrees. AND Pain at night. PLUS

3. Objective Clinical Findings: Weak or absent abduction; may also demonstrate atrophy. AND Tenderness over rotator cuff or anterior acromial area. AND Positive impingement sign and temporary relief of pain with anesthetic injection (diagnostic injection test). PLUS

4. Imaging Clinical Findings: Conventional X-Rays, AP, and true lateral or axillary view. AND Gadolinium MRI, ultrasound, or arthrogram shows positive evidence of impingement.

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)