Health Decisions, Inc.

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Notice of Independent Review Decision

June 16, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Left Shoulder Arthroscopy with Open Rotator Cuff Repair and Subacromial Bursectomy

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

This physician is Board Certified in Orthopedic Surgeon with over 40 years of experience.

REVIEW OUTCOME:

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

☒ Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male that was injured at work on xx/xx/xx. He fell landing on his left arm and shoulder. When he tried to catch himself, he heard a loud pop in his left shoulder and has had increasing pain and swelling since. The claimant has had 2 rotator cuff repairs, left shoulder scope with SLAP repair, a shoulder arthroscopy with subacromial decompression and acromloplasty and an undetermined amount of PT sessions all without any resolution of left shoulder pain.

06-07-12/06-20-12: Encounter Summary with Amendment. The claimant presented with a work injury left shoulder problem. He states pain quality aching,

burning, gnawing, stabbing, throbbing, sharp, deep and constant. He claims his left shoulder pain is moderate to severe. His associated Sx are weakness, swelling, redness, catching/locking, popping/clicking and instability. The claimant states PT did not help and has decreased ROM and inability to raise his arm up without extreme pain. Upon examination, the claimant's active ROM in left shoulder is forward flexion (45 deg.) and abduction (45 deg.) and internal rotation and adduction to T8. Passive ROM: Forward flexion (120 deg.) and abduction (120 deg.). Special Tests: Near test positive, pain with cross-body adduction, Hawkin test positive and positive arm drop. Strength: External rotation of 0 deg. of abduction 5/5 and 90 deg. of abduction 5/5 and general strength 5/5, adduction 5/5, extension 5/5, abduction 5/5, internal rotation 5/5 and scapular elevation 5/5. Assessment/Plan: 1. Sprains and strains of shoulder and upper arm; rotator cuff (capsule); unspecified side of shoulder and upper arm.

06-08-12: Operative Report. Preoperative Dx: 1. Left shoulder rotator cuff tear. 2. Left shoulder labral tear. 3. Left shoulder intraarticular synovitis. Postoperative Dx: Same. Procedure: 1. Left shoulder arthroscopy. 2. Subacromial decompression. 3. Bursectomy repair superior labral anterior posterior lesion using two Mitek bioabsorbable anchors. 4. Intraarticular synovectomy. 5. Mini-open rotator cuff repair using two Mitek G4 anchors and one Versalok anchor. We injected liquid amnio into the joint and lay UN AmnioShield over the rotator cuff repair.

06-21-12: Encounter Summary. The claimant c/o severe left shoulder pain that has no associated symptoms, however, arrived with a sling and no bump. The claimant had sutures removed from left upper shoulder. The stitches appear intact, clean, without s/s of infection and incision healing well. Assessment/ Plan: Claimant to begin therapy in 2 weeks – 2-3 visits per week for 4 weeks and to continue home exercise.

08-02-12: Encounter Summary. The claimant is here for f/u on unspecified shoulder strain and shoulder rotator cuff tear. He reports improving left shoulder pain that continues to have popping/clicking in the joint. The claimant arrives in a sling and bump and is currently attending PT. Assessment/Plan: Continue PT and provide aggressive ROM and continue sling for comfort only.

08-20-12: MRI of the Left Shoulder without Contrast. Impression: Recurrent full thickness rotator cuff tear of the supraspinatus following rotator cuff repair.

08-30-12: Encounter Summary. The claimant c/o mild left shoulder pain that has decreasing ROM. Upon examination, left shoulder active ROM as follows: Forward flexion (80 deg.) and abduction (45 deg.). Assessment/Plan: Order a repeat MRI and discontinue PT d/t have not changes or shown any improvement in patients ROM.

09-05-12: MRI of the Left Shoulder without Contrast. Impression: The supramephlalus portion of the rotator cuff is torn 1.1 cm retraction of the tendon is

demonstrated at the site of tear and a small joint effusion is present. Moderate degenerative changes as seen in the left acromiaclavicular joint.

10-11-12: Encounter Summary. The claimant c/o left shoulder weakness, popping/clicking and instability. Upon examination, passive ROM is limited in left shoulder. Left shoulder special tests: Positive O'Brien test, Neer test, Hawkin test and Speed test. Assessment/Plan: Claimant advised on RICE therapy and instructed to continue with his home exercises.

11-14-12: Encounter Summary. Upon examination of the claimant, left shoulder active ROM: Limited, forward flexion (80 deg.), and abduction (45 deg.). Passive ROM: Limited. Assessment/Plan: Recommended surgical intervention that will include a left shoulder rotator cuff repair.

11-29-12: Encounter Summary. The claimant presents with varying mild to moderate left shoulder pain. He reports weakness, tingling (only while in sling for long periods of time), and instability of the left shoulder. The claimant had left shoulder open RTC repair on 11-16-12. He removed sling while in the room waiting to see provider. Procedure Documentation: Sutures removed and site WNL. Assessment/Plan: The claimant is to start PROM 1 week, AAROM 1 week, AROM for two weeks after that, to start in two weeks from today.

01-03-13: Encounter Summary. The claimant presents with mild, improving left shoulder pain, although ROM is not improving. Upon examination, the claimant Left Shoulder AROM: Limited, forward flexion (45 deg.), and abduction (60 deg.). Left Shoulder PROM: Limited. Assessment/Plan: Given RX for Norco 10mg/325mg and PT. He is to continue HEP and to be WBAT.

03-21-13: Encounter Summary. The claimant presents with left shoulder improving, but with some burning pain. He c/o weakness and swelling, however, he states he is doing well with improving ROM and has 7 sessions of PT left. Upon examination, the claimant's left shoulder AROM is limited with forward flexion (160 deg.) and abduction (160 deg.). Assessment/Plan: He is doing well and is to continue with PT more aggressively.

04-25-13: Encounter Summary. The claimant reports left shoulder improving ROM and states he is doing well. He has 7 sessions of PT left. Upon examination, left shoulder AROM WNL, Left shoulder stability: Anterior relocation test negative, apprehension test negative, load & shift test negative, posterior apprehension test negative and sulcus sign negative. Strength: external rotation at 0 deg. of abduction 5/5, 90 dorsal abduction 5/5, abduction 5/5, extension 5/5, flexion 5/5, general strength 5/5, internal rotation 5/5 and scapular elevation 5/5. Assessment/Plan: The claimant is doing well.

06-20-13: Encounter Summary. The claimant presents stating that he was at PT and felt a pop in his left shoulder and he had sudden onset of pain. He also c/o numbness and tingling in his arm and hand from the elbow down. Upon examination, bony palpitation on left shoulder had tenderness of the

acromioclavicular joint and acromial. AROM: Limited with forward flexion (110 with pain from 90 to 100 deg.) and abduction (100 with pain from 90-100 deg.). PROM: Limited. Special Tests: Hawkin test positive, Neer test positive and O'Brien test positive. Strength: General strength 3/5. Procedure Documentation: Left shoulder subacromial space cortisone injection.

07-23-13: MRI Arthrogram Left Shoulder, Resident. Impression: 1. Prior repair of the supraspinatus and infraspinatus tendons. 2. Full thickness tear of the anterior edge of the supraspinatus tendon insertion with 1.5cm of tendon retraction. Posterior aspect of the supraspinatus tendon is moderately thin but intact. Normal appearance of the intraspinatus tendon insertion. Minimal atrophy of the supraspinatus and infraspinatus muscles. 3. Moderate long head biceps tendonopathy. 4. Extensions of glenohumoral contrast material through the rotator cuff defect into the subacromial subdeltoid bursac, the into acromiaclavicular joint, which is abnormally wide.

08-01-13: Encounter Summary. The claimant c/o left aching, gnawing, stabbing, throbbing, sharp, constant and worsening shoulder pain. Upon examination, claimant has left shoulder tenderness of the acromioloclavicular joint and acromial upon bony palpation. AROM: Limited, forward flexion (100 with pain from 90 deg.), internal rotation at 90 deg. of abduction (IC deg.), and abduction (95 with pain from 90 deg.). PROM: Limited. Assessment/Plan: The claimant can bear weight as tolerated and surgical intervention (left shoulder open rotator cuff) was recommended and agreed upon.

09-26-13: Encounter Summary. Upon examination, the claimant has decreased sensation of the 4th and 5th digits, ulnar hand and distal forearm on the left.

10-15-13: Encounter Summary. The claimant c/o moderate left shoulder pain, otherwise no changes.

10-18-13: Operative Report. Preop Dx: Recurrent tear, left rotator cuff. Postop Dx: Same. Procedure: Open rotator cuff repair using two Biomet bioabsorbable anchors and two Versalok anchors.

10-28-13: Encounter Summary. The claimant presents postoperatively after his 3rd RTC repair on the left shoulder. He is doing ok and needs suture removal. Sutures were removed w/o incident. Assessment/Plan: The claimant is to stay in the sling and start PT 11-29-13.

12-05-13: Encounter Summary. The claimant c/o moderate left shoulder pain, states he went to PT 11-29-13 and caused pain to increase. Upon examination, left shoulder, AROM: Limited, forward flexion (100 with pain from 90 deg.), internal rotation at 90 deg. of abduction (IC deg.) and abduction (pain from 90 deg.). PROM: Limited. Special Tests: WNL. General strength – 3/5. Sensation on the Left: decreased sensation of the 4th and 5th digits, ulnar hand and distal forearm. Assessment/Plan: Continue with PT.

01-06-14: Encounter Summary. The claimant states that on 12-19-13 he was reaching in his pocket to get something and felt a large pop and had sudden onset of pain. A new MRI was ordered, but the claimant has not had it done yet. Upon examination, AROM: Forward flexion (80 deg.). Special Tests: Hawkin and Neer test positive. Assessment/Plan: Scheduled for MRI 01-10-14.

01-09-14: Fluoroscopically Directed Left Shoulder Arthrogram, Radiologist. Impression: 1. Left shoulder arthrogram in preparation for left shoulder MRI evaluation. No complicating process is noted. 2. Evidence of recurrent rotator cuff tear.

01-09-14: MRI Left Shoulder with Contrast M R Arthrogram. Impression: 1. Prior repair of the supraspinatus and infraspinatus tendons, with interval surgical interventions. 2. Improved appearance of the supraspinatus tendon. A full thickness defect of the anterior most fibers persist. However, when compared to the prior study and the anterior aspect of the tendon which demonstrated a full thickness tear on the prior exam has improved appearance on today's study. The portion of the tendon is thinned but a full thickness defect in this region is not identified. 3. Tendonosis of the subacapularis tendon with low-grade cranial fiber tear. 4. Illegible (MRI Report to be attached). 5. Volume loss and Grade 1 fatty infiltration of the supraspinatus and infraspinatus muscles.

02-13-14: Encounter Summary. The claimant states PT is not going well, he is having a lot of left shoulder pain and everyone is telling him he is going to need a shoulder replacement. Upon examination, AROM: limited and forward flexion (45 deg.). Special tests: Hawkin, O'Brien and Speed test positive. Assessment/Plan: Continue RICE therapy, home exercises and D/C PT at this time.

03-20-14: Encounter Summary. Upon examination, AROM: limited and forward flexion (60 deg.) with subscapularis weakness. Mild atrophy present significant ROM loss is present. Neurological system WNL. Assessment/Plan: Recommend surgical intervention that will include a left shoulder arthroscopy with rotator cuff debridement versus repair with SAD bursectomy.

04-14-14: URA. Rationale: The guideline criteria have not been met. As noted above, the patient does show continued shoulder pain, which was helped slightly by the previous PT, and tenderness of the bicipital groove, supraspinatus, and deltoid are noted. Furthermore, the patient's range of motion is limited with forward flexion at 60 degrees and subscapularis weakness is noted. However, evidence of a recent comprehensive non-operative treatment protocol trial and failure (along with the newest MRI) has not been submitted. Therefore, based on ODG, this request for subacromial bursectomy is not medically reasonable or necessary at this time.

05-13-14: URA. Rationale: The documentation indicates the patient having ongoing complaints of left shoulder pain with associated range of motion deficits. Given the definitive findings revealed on the most recent MRI of the left shoulder, this request is not indicated. Therefore, the left shoulder arthroscopy was not

medically necessary. Given the patient's 2 previous surgeries at the left shoulder, it is unlikely the patient would benefit from a 3rd surgery. Therefore, the subacromial bursectomy was not medically necessary.

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

The previous decisions are overturned. The claimant apparently had an event on 1-6-14 that involved a popping sensation and pain in his left shoulder, then on 1-9-14 had an MRI-arthrogram showing an anterior full thickness tear. The claimant has documented limited range of motion in forward flexion (60 deg.) with subscapularis weakness. Mild atrophy is also present. The claimant underwent PT which was unsuccessful and continues with should pain. Although recurrent tears with multiple surgeries have a history of poor results, I believe surgery is indicated in this case. Therefore, the request for Left Shoulder Arthroscopy with Open Rotator Cuff Repair and Subacromial Bursectomy is certified.

Per ODG:

Surgery for rotator cuff repair	Recommended as indicated below. Repair of the rotator cuff is indicated for significant tears that impair activities by causing weakness of arm elevation or rotation, particularly acutely in younger workers. However, rotator cuff tears are frequently partial-thickness or smaller full-thickness tears. For partial-thickness rotator cuff tears and small full-thickness tears presenting primarily as impingement, surgery is reserved for cases failing conservative therapy for three months. The preferred procedure is usually arthroscopic decompression, but the outcomes from open repair are as good or better. Surgery is not indicated for patients with mild symptoms or those who have no limitations of activities. (Ejnisman-Cochrane, 2004) (Grant, 2004) Lesions of the rotator cuff are best thought of as a continuum, from mild inflammation and degeneration to full avulsions. Studies of normal subjects document the universal presence of degenerative changes and conditions, including full avulsions without symptoms. Conservative treatment has results similar to surgical treatment but without surgical risks. Studies evaluating results of conservative treatment of full-thickness rotator cuff tears have shown an 82-86% success rate for patients presenting within three months of injury. The efficacy of arthroscopic decompression for full-thickness tears depends on the size of the tear; one study reported satisfactory results in 90% of patients with small tears. A prior study by the same group reported satisfactory results in 86% of patients who underwent open repair for larger tears. Surgical outcomes are much better in younger patients with a rotator cuff tear, than in older patients, who may be suffering from degenerative changes in the rotator cuff. Referral for surgical consultation may be indicated for patients who have: Activity limitation for more than three months, plus existence of a surgical lesion; Failure of exercise programs to increase range of motion and strength of the musculature around the shoulder, plus existence of a surgical lesion; Clear clinical and imaging evidence of a lesion that has been shown to benefit, in both the short and long term, from surgical repair; Red flag conditions (e.g., acute rotator cuff tear in a young worker, glenohumeral joint dislocation, etc.). Suspected acute tears of the rotator cuff in young workers may be surgically repaired acutely to restore function; in older workers, these tears are typically treated conservatively at first. Partial-thickness tears are treated the same as impingement syndrome regardless of MRI findings. Outpatient rotator cuff repair is a well accepted and cost effective procedure. (Cordasco, 2000) Difference between surgery & exercise was not

	significant. (Brox, 1999) There is significant variation in surgical decision-making and a lack of clinical agreement among orthopaedic surgeons about rotator cuff surgery. (Dunn, 2005) For rotator cuff pain with an intact tendon, a trial of 3 to 6 months of conservative therapy is reasonable before orthopaedic referral. Patients with small tears of the rotator cuff may be referred to an orthopaedist after 6 to 12 weeks of conservative treatment. (Burbank2, 2008) Patients with workers' compensation claims have worse outcomes after rotator cuff repair. (Henn, 2008) *Revision rotator cuff repair:* The results of revision rotator cuff repair are inferior to those of primary repair. While pain relief may be achieved in most patients, selection criteria should include patients with an intact deltoid origin, good-quality rotator cuff tissue, preoperative elevation above the horizontal, and only one prior procedure. (Djurasovic, 2001) *Recent research:* Evidence on the pros and cons of various operative and nonoperative treatments for rotator cuff tears is limited and inconclusive, an AHRQ comparative effectiveness review concluded. While the data are sparse, patients improved substantially with all interventions; there were few clinically important differences between approaches, and complications were rare. Most patients try to resolve their pain and disability with a course of physical therapy before attempting surgery, but the study found very little good quality research to guide the choice of nonoperative treatment, the timing of treatment, and who would most benefit from various forms of treatment. Four out of five studies comparing surgical and nonsurgical management favored operative repair, but the evidence was too limited to make conclusions regarding comparative effectiveness. 113 studies comparing various operations found no differences in functional outcomes between open vs mini-open repair, mini-open vs arthroscopic repair, arthroscopic repairs with vs without acromioplasty, and single-row vs double-row fixation. Patients who had mini-open repair returned to work about a month earlier than patients who had open repair. On the other hand, functional improvement was better after open repair compared with arthroscopic debridement. With regard to adding continuous passive motion to postoperative physical therapy, 11 trials yielded moderate evidence for no difference in function or pain. One study found no difference in range of motion or strength, while another suggested that adding continuous passive motion shortened the time until return to work and the time to 90 degrees abduction. For other postoperative rehabilitation strategies, one study showed that progressive loading reduced pain compared to traditional loading. In general, though, most studies found no difference in health-related quality of life, function, pain, range of motion, and strength with one approach versus another (e.g., with or without aquatics, individualized vs at home alone, videotape vs therapist-based, etc.). In the 72 studies that assessed prognostic factors, older age, increasing tear size, and greater preoperative symptoms were consistently associated with recurrent tears, whereas gender, workers' compensation status, and duration of symptoms usually did not predict poorer outcomes. (Seida, 2010) "Rotator cuff surgery is a viable option for many patients, but, as with any surgery, it is not for everybody," said AHRQ Director Carolyn M. Clancy, M.D. "This report has good news: most interventions work, and each patient should talk to his or her doctor about which to option to pursue." Most older patients who suffer a rotator cuff tear are first treated with up to 3 months of nonsurgical treatment such as pain and anti-inflammatory medications, exercise, and rest. If treatments other than surgery do not work, the rotator cuff may be repaired surgically, using a variety of methods ranging from minimally invasive techniques to an open operation. Patients can then undergo rehabilitation to restore their range of motion, muscle strength, and function following surgery. Rotator cuff tears also can occur in younger adults, usually as a result of traumatic injury. In such cases they are almost always treated with surgery. Some doctors have maintained that earlier surgery results in less pain and better use of the shoulder, leading to an earlier return to work and decreased costs; so, patients often face the difficult decision of opting for surgery rather than waiting for nonoperative treatments to work. However, researchers found little evidence that earlier surgery benefits patients. Comparative Effectiveness of

	Nonoperative and Operative Treatments for Rotator Cuff Tears is the newest comparative effectiveness report from the AHRQ's Effective Health Care Program. The Effective Health Care Program represents the leading federal effort to compare alternative treatments for health conditions and make the findings public, to help doctors, nurses, pharmacists and others work together with patients to choose the most effective treatments. (Clancy, 2010) This prospective cohort study concluded that PT is effective for most patients with atraumatic full-thickness rotator cuff tears and shoulder pain, without the need for surgery. At six weeks fewer than 10% of patients had decided to undergo surgery, and after 2 years, only 2% of the rest had opted for surgery. Patients did most of their physical therapy at home and usually made only 1 weekly visit to the physical therapist. (Kuhn, 2011) One-third of rotator cuff repairs fail, and 74% of the failures occur within three months of surgery. Healed tendons, or recurrent tears, at six months can predict outcomes at seven years. (Kluger, 2011) Not surprisingly, larger tears are harder to repair, and the retear rate based on rotator cuff tear size is: 10% for ≤2 cm2; 16% for 2–4 cm2; 31% for 4–6 cm2; 50% for 6–8 cm2; & 57% for >8 cm2. (Murrell, 2012) There is insufficient evidence to suggest efficacy in operative or nonoperative treatment of rotator cuff tears in in patients aged older than 60 years. (Downie, 2012) **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. (Washington, 2002) For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

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)**