INDEPENDENT REVIEWERS OF TEXAS, INC.

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[Date notice sent to all parties]:

11/24/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Right shoulder AS SAD possible open rotator cuff repair, open distal clavicle resection.

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

REVIEW OUTCOME:

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

☒ 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]:

Patient is a male with a reported date of injury of XX/XX/XX. On XX/XX/XX, he was seen in clinic. He described falling at work injuring his right shoulder. He stated his pain was mostly to his lateral deltoid. He denied numbness, tingling or radicular pain. On exam, he had 30 degrees of active forward flexion and abduction, and he had a positive apprehension sign. X-rays of the right shoulder were within normal limits without fractures. He did have a type 2 acromion. On 09/15/15, the patient returned to clinic. He still reported lots of pain to his shoulder, and on exam he had 140 degrees of forward flexion and 100 degrees of abduction with pain. He had a positive apprehension sign. Noting he had failed conservative measures, a right shoulder arthroscopy, probable open rotator cuff repair, subacromial decompression and distal clavicle resection was recommended.

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

On 09/18/15, a utilization review request review was noted for the right shoulder arthroscopic exam, subacromial decompression, possible open rotator cuff repair, open distal clavicle resection, and the request was non-certified. That review utilized Official Disability Guidelines shoulder chapter, as the reference source. It was noted that an unofficial MRI was reviewed when the patient was seen in clinic, showing the pathology. Conservative measures were indicated as being performed. It was noted then that clarification was needed regarding the unchanged physical examination findings, and there was no documented night pain or painful arc of motion to support the requested surgery. The official MRI was not provided and it was unclear if the patient had received an adequate trial of conservative care.

On 10/05/15, a notification of reconsideration determination was submitted for the requested services. The Official Disability Guidelines, shoulder chapter was utilized as the reference source. It was noted there was agreement with the previous determination and medical necessity for the requested procedure has not been substantiated. There was no evidence in the records that the patient had failed at least 3-6 months of conservative treatment prior to the proposed surgery. Therefore the request was non-certified.

For this review, imaging studies documenting the pathology have not been provided. Recent attempts at conservative care need to be clarified. Therefore, it is the opinion of this reviewer that the request for Right shoulder AS SAD possible open rotator cuff repair, open distal clavicle resection is not medically necessary and the prior denials are upheld.

IRO REVIEWER REPORT TEMPLATE -WC

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

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

☒ ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

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. "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) In this RCT, full-thickness rotator cuff repair outcomes were the same, with or without acromioplasty. Acromioplasty is commonly performed during arthroscopic rotator cuff repair, but it does not improve outcomes by 2-year follow-up. (Abrams, 2014) Non-contrast MRI is sufficient for rotator cuff tears, and contrast enhancement is recommended for SLAP tears. (Spencer, 2013) (Farshad-Amacker, 2013) (Arnold, 2012) (Major, 2011) See also Stem cell autologous transplantation (shoulder).

ODG Indications for Surgeryä -- 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 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 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).