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Notice of Independent Review Decision

[Date notice sent to all parties]:

02/06/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Right shoulder decompression, acromioclavicular joint resection, possible rotator cuff repair, and possible labral repair with pain pump

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

MRI right shoulder 07/02/13
Clinical notes 09/04/13
Clinical notes 09/10/13
Clinical notes 09/18/13
Clinical notes 10/21/13
Clinical notes 10/23/13
Therapy notes 10/31/13

Therapy notes 11/04/13
Therapy notes 11/06/13
Therapy notes 11/20/13
Therapy notes 11/21/13
Clinical notes 11/22/13
Clinical notes 11/26/13
Therapy notes 12/05/13
Therapy notes 12/10/13
Clinical notes 12/11/13
Adverse determinations 12/18/13 and 01/06/14

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who reported an injury to her right shoulder after a fall. MRI of the right shoulder dated 07/02/13 revealed a laterally downsloping acromion process potentially producing impingement. Acromiohumeral distance was well preserved. Mild rotator cuff tendinosis with no evidence of tear was noted. Small amount of fluid was noted in the subacromial subdeltoid bursa suggesting mild bursitis. Tendinosis was mild at the supraspinatus and infraspinatus tendons. Clinical note dated 09/04/13 indicated the patient continuing with complaints of right shoulder pain. The patient stated she was having difficulty sleeping at night secondary to the pain level. The patient initiated physical therapy. Therapy note dated 10/31/13 indicated the patient undergoing multiple modalities to address right shoulder complaints. Clinical note dated 12/10/13 indicated the patient completing six weeks of treatment. Clinical note dated 12/11/13 indicated the patient continuing with right shoulder pain. The patient described the pain as sharp with moderate intensity. The patient underwent steroid injection at the right shoulder with no significant benefit. The patient had positive Neer and Hawkins signs. Tenderness was noted at the bicipital groove. The patient had normal tone with no noted atrophy. The patient was recommended for right shoulder arthroscopy with a rotator cuff repair, acromioclavicular joint resection, and subacromial decompression. Utilization review dated 12/18/13 resulted in denial for the requested procedures as the patient was noted to have no limitations with activities. Utilization review dated 01/06/14 resulted in denial for the right shoulder procedures as the symptoms were mild in nature and not likely to benefit from a surgical procedure.

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

Clinical documentation submitted for review notes the patient complaining of right shoulder pain. A subacromial decompression, acromioclavicular joint resection, rotator cuff repair, and labral repair would be indicated provided that the patient meets specific criteria, including completion of a three month course of conservative treatment and imaging studies confirming pathology. Submitted MRI revealed no rotator cuff involvement. No tears were noted at the labrum.

Additionally, it is unclear if the patient completed a full three month course of treatment addressing right shoulder complaints. Given these findings, a surgical procedure at the right shoulder would be appropriate for this patient at this time. As such, it is the opinion of this reviewer that the requested surgical procedures including rotator cuff repair and subacromial decompression are not recommended.

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 impingement syndrome

Recommended as indicated below. Surgery for impingement syndrome is usually arthroscopic decompression (acromioplasty). However, this procedure is not indicated for patients with mild symptoms or those who have no limitations of activities. Conservative care, including cortisone injections, should be carried out for at least three to six months prior to considering surgery. Since this diagnosis is on a continuum with other rotator cuff conditions, including rotator cuff syndrome and rotator cuff tendonitis, see also Surgery for rotator cuff repair. (Prochazka, 2001) (Ejnisman-Cochrane, 2004) (Grant, 2004) Arthroscopic subacromial decompression does not appear to change the functional outcome after arthroscopic repair of the rotator cuff. (Gartsman, 2004) This systematic review comparing arthroscopic versus open acromioplasty, using data from four Level I and one Level II randomized controlled trials, could not find appreciable differences between arthroscopic and open surgery, in all measures, including pain, UCLA shoulder scores, range of motion, strength, the time required to perform surgery, and return to work. (Barfield, 2007) Operative treatment, including isolated distal clavicle resection or subacromial decompression (with or without rotator cuff repair), may be considered in the treatment of patients whose condition does not improve after 6 months of conservative therapy or of patients younger than 60 years with debilitating symptoms that impair function. The results of conservative treatment vary, ongoing or worsening symptoms being reported by 30-40% patients at follow-up. Patients with more severe symptoms, longer duration of symptoms, and a hook-shaped acromion tend to have worse results than do other patients. (Hambly, 2007) A prospective randomised study compared the results of arthroscopic subacromial bursectomy alone with debridement of the subacromial bursa followed by acromioplasty in patients suffering from primary subacromial impingement without a rupture of the rotator cuff who had failed previous conservative treatment. At a mean follow-up of 2.5 years both bursectomy and acromioplasty gave good clinical results, and no statistically significant differences were found between the two treatments.

The authors concluded that primary subacromial impingement syndrome is largely an intrinsic degenerative condition rather than an extrinsic mechanical disorder. (Henkus, 2009) A recent RCT concluded that arthroscopic acromioplasty provides no clinically important effects over a structured and supervised exercise program alone in terms of subjective outcome or cost-effectiveness when measured at 24 months, and that structured exercise treatment should be the basis for treatment of shoulder impingement syndrome, with operative treatment offered judiciously. (Ketola, 2009)

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.

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 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 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).