CASEREVIEW

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Notice of Independent Review Decision

[Date notice sent to all parties]: September 29, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Right Shoulder Arthroscopy with Open Repair of Subscapularis with Stem Cells and Purchase of Cold Therapy Unit and Sling Shot

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
This physician is a Board Certified 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:
05/15/13: History and Physical
05/17/13: MR Arthrogram of the Right Shoulder
05/22/13: Follow-up Evaluation
05/29/13: UR performed
06/12/13: Follow-up Evaluation
06/26/13: 2nd Opinion
07/30/13: UR performed
08/21/13: Follow-up Evaluation

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant is a male who sustained and injury on xx/xx/xx when he subsequently felt pain in his right shoulder. It was noted that his shoulder was in an extended abducted and internally rotated position.

On May 15, 2013, the claimant was evaluated for right shoulder pain rated 8/10. He described difficulty with performing things out to the side or behind his back, but had no difficulty doing thing in front even flexion above his chest level. On physical examination, passively he had full range of motion. With internal rotation he had difficulty getting his arm around his back actively, but passively they could bring his arm up his back without difficulty. Impingement maneuvers, Neer, and Hawkins were negative. Strength testing of the rotator cuff revealed he had great strength to external rotation and empty beer can testing; however, abdominal squeeze test was significantly positive. He could not even push his hand into his abdomen at all secondary to weakness. Liftoff test was also grossly positive. Speed's and Yergason's tests were negative. Apprehension was negative. He had some mild tenderness over the lesser tuberosity to palpation and also in the bicipital groove. Brachioradialis reflexes were brisk and symmetrical to the opposite side. He had good motor testing throughout the bicep, triceps, wrist extensor, wrist flexors, hand intrinsic, and finger flexors. X-rays of the right shoulder revealed no fractures, dislocations, subluxations, neoplastic lesions, or joint line narrowing. Impression: Subscapularis tear. Plan: MRI.

On May 17, 2013, MR Arthrogram of the Right Shoulder, Impression: 1. Full-thickness tear of the subscapularis tendon with severe atrophy and fatty infiltration within its muscle belly. 2. Partial undersurface tear involving the infraspinatus tendon at its insertion site. 3. Supraspinatus insertional tendiopathy without tear. 4. SLAP type II tear. 5. Mild AC joint hypertrophy and a small subacronimal spur impinge the supraspinatus musculotendinous junction.

On May 22, 2013, the claimant was re-evaluated. reviewed the MRI and recommended an open subscapularis repair and because of the fatty infiltration, also recommended the harvesting stem cells from his bone marrow with a bone marrow aspirate with spinning down of the cells, centrifuge, and reinjection of stem cells into the muscle belly complex.

On May 29, 2013, completed a UR. Rational for Denial: The guidelines state surgery for rotator cuff repair is indicated with a diagnosis for full-thickness tear when subjective clinical findings of shoulder pain, inability to elevate the arm, and tenderness over the greater tuberosity are noted. No complaints of inability to elevate the arm were noted. Objective clinical findings of weakness with abduction and atrophy of the shoulder musculature should be noted. No physical examination findings were documented. The guidelines also state that stem cell autologous transplantation may have a positive effect on tendon healing and continue flow cryotherapy is recommended as an option after surgery; however, the need for right shoulder arthroscopy with open repair of subscapularis tendon is not supported based on the lack of physical examination findings in the provided medical records. The request for right shoulder arthroscopy with open repair of subscapularis with stem cells and purchase of cold therapy unit and sling shot is not certified.

On June 12, 2013, the claimant was re-evaluated who noted the claimant had no shoulder deficits until he injured his shoulder on the job. It was noted his physical examination was consistent with a torn subscapularis with a positive squeeze test and a positive lift-off test. presented his argument that the conventional disability guidelines only address when the supraspinatus or infraspinatus are torn and do not address the subscapularis, which is also an important muscle and shoulder function. He continued to state that the clamant would not benefit from physical therapy with a full thickness subscapularis rupture and that the stem cell autologous transplantation is recommended because of the severe atrophy in the muscle and possible death of the muscle, which may lease to a failure of the tendon surgery if not used.

On June 26, 2013, the claimant was evaluated for right shoulder pain and symptoms that are made worse with lifting more than 5-10 pounds and motion. It was also reported the claimant was having difficulty sleeping because of pain. On physical examination Lift Off was positive and noted that he was unable to perform. Impingement signs: Neer, Hawkins, Xbody, and internal impingement sings were negative. There was weakness of internal rotators. Speeds test was negative. Plan: Recommended to have his subsacp rotator cuff tear fixed by either himself or, sooner rather than later to avoid further atrophy.

On July 30, 2013, completed a UR. Rational for Denial: The claimant was noted to have significant findings on the MRI study of the shoulder including a subscapularis tear; however, this appears to be chronic with severe atrophy and fatty infiltration documented. Since the claimant has multiple findings and has not undergone any conservative treatment (physical therapy, oral medications, or injections to the shoulder) and the findings indicate chronic changes, surgical intervention at this time prior to resorting to any type of conservative treatment does not appear to be indicated. Since the surgery is not indicated, there is subsequently no indication for the use of stem cells or the purchase of a postoperative therapy cold unit or use of a sling shot. The treatment guidelines would support the rental of a cold therapy unit for seven days following surgical intervention, but since the surgery is not certified, the device is not deemed to be medically indicated. A sling would also be certified to repair massive rotator cuff tear and appears to be within reason; however, as the surgical intervention is not certified, the request for a sling is also not certified. In regards to the stem cell request, as the use of stem cell autologous transplantation is noted to be under study at this time, the use of stem cell transplantation is not supported by the treatment guidelines. Based on all of the above factors, the treating provider's request is not certified.

On August 21, 2013, the claimant was re-evaluated who to appease the prior Reviewers documented a grade for the weakness to a squeeze test. For both the squeeze test and lift-off test he was documented to be a 3/5 grade. opined that the claimant has a severe injury that needs to be repaired or it can detrimentally affect his shoulder irreversibly leading to further more severe surgeries.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
The previous adverse determinations are overturned. The MR Arthrogram of the right shoulder on May 17, 2013 demonstrated a full-thickness tear of the subscapularis tendon with severe atrophy and fatty infiltration within its muscle belly and a partial undersurface tear involving the infraspinatus. The atrophy and fatty infiltrate indicate a serious tear not likely to heal spontaneously and will become harder to repair if put off. Therefore, the ODG criteria for conservative care is not relevant in this case. The documented objective clinical findings of a positive squeeze test and a positive lift-off test, both graded 3/5, are consistent with the subscapularis tear. It is in my opinion that the request for right shoulder arthroscopy with open repair of subscapularis does meet ODG criteria, sans the conservative care, which would not be appropriate in this specific case, and therefore is approved.

Although the treatment guidelines indicates the use of stem cell autologous transplantation is under study at this time, it also stated that that stem cell autologous transplantation may have a positive effect on tendon healing. I agree that in this particular case, with severe atrophy in the muscle, stem cell autologous transplantation is necessary.

The ODG also supports the rental of a cold therapy unit for up to seven days following surgical intervention. The sling is also recommended by ODG as an option following open repair of a large rotator cuff repair. Therefore, the complete request for Right Shoulder Arthroscopy with Open Repair of Subscapularis with Stem Cells and Purchase of Cold Therapy Unit and Sling Shot is found to be medically necessary and approved.

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).

Stem cell autologous transplantation	Under study, with some initial promise from lower quality trials. The current evidence shows that stem cells can have a positive effect on tendon healing. This is most likely because stem cells have regeneration potential, producing tissue that is similar to the preinjury state, but the results can be variable. (Ahmad, 2012) Repair of rotator cuff tears in experimental models has been significantly improved by the use of enhanced biologic approaches, including platelet-rich plasma, bone marrow aspirate, growth factor supplements, and cell- and gene-modified cell therapy. Bone marrow-derived mesenchymal stem cells provide a stimulus for repair in flexor tendons, but application in rotator cuff repair has not shown universally positive results. (Nixon, 2012) The combination of stem cells and growth factors resulted in enhanced repair that emulated uninjured tissue, but the literature search reflected paucity of research in this field. (Isaac, 2012) Implantation of autologous bone marrow mononuclear cells in rotator cuff sutures appears to be a safe and promising alternative to other biological approaches. (Ellera, 2012) With the limitation of the available evidence, the literature suggests that cell therapy is applicable and may be effective for the treatment of tendinopathy. (Obaid, 2010)

Continuous-flow cryotherapy	Recommended as an option after surgery, but not for nonsurgical treatment. Postoperative use generally may be up to 7 days, including home use. In the postoperative setting, continuous-flow cryotherapy units have been proven to decrease pain, inflammation, swelling, and narcotic usage; however, the effect on more frequently treated acute injuries (eg, muscle strains and contusions) has not been fully evaluated. Continuous-flow cryotherapy units provide regulated temperatures through use of power to circulate ice water in the cooling packs. Complications related to cryotherapy (i.e, frostbite) are extremely rare but can be devastating. (Hubbard, 2004) (Osbahr, 2002) (Singh, 2001) See the Knee Chapter for more information and references.

Postoperative abduction pillow sling	Recommended as an option following open repair of large and massive rotator cuff tears. The sling/abduction pillow keeps the arm in a position that takes tension off the repaired tendon. Abduction pillows for large and massive tears may decrease tendon contact to the prepared sulcus but are not used for arthroscopic repairs. (Ticker, 2008)

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)**