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Notice of Independent Review Decision

October 5, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Left shoulder reverse arthroplasty

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

Certified by the American Board of Orthopaedic Surgery

REVIEW OUTCOME:

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

Overturned (Disagree)

Medical documentation supports the medical necessity of the health care services in dispute.

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 patient is a male who sustained an injury to his left shoulder on xx/xx/xx.

Prior to the DOI, a MRI of the right shoulder without contrast on September 23, 2011, demonstrated complete tear of the supraspinatus tendon with 1 cm of medial retraction, complete tear of the subscapularis tendon with retraction of the glenohumeral joint, severe atrophy of the subscapularis muscle, rim rent tear of the infraspinatus tendon, complete tear of the bicipital labral complex with tenodesis of the biceps tendon within the intertubercular groove, severe acromioclavicular (AC) arthropathy with a type 2 acromion, moderate anterior downsloping and rotator cuff interval lesion.

On February 10, 2014, an **MRI of the left shoulder** without contrast showed full-thickness tear of the supraspinatus tendon including the anterior infraspinatus, large volume bursal fluid, type 2 acromion. The rest of the report is largely illegible.

On March 28, 2014, the patient underwent left shoulder arthroscopic rotator cuff repair, biceps tenodesis and extensive debridement. The postoperative diagnoses were massive rotator cuff tear, biceps tendon tear with tenosynovitis,

extensive labral tears and degenerative disc disease (DJD).

About 11 months later, on February 12, 2015, evaluated the patient for left shoulder pain described as dull, constant, and improved with rest. Previous treatments had included physical therapy (PT) and surgery. The patient stated he was doing exercises at home and was not having any real pain, but discomfort occasionally into the upper arm. He would intermittent pain across the biceps area in the mid shaft of the arm. On examination, the left shoulder showed clean, dry and intact incisions; mild tenderness, moderately decreased range of motion (ROM). He could actively elevate the arm and hold it against gravity. Forward flexion was 180 degrees. The diagnoses were rotator cuff sprain/strain/tear; bicipital tenosynovitis, left; articular cartilage disorder, shoulder; DJD of the AC joint. stated the patient was making good progress overall and should go back to light duty status.

Three months later, on May 16, 2015, the patient returned for occasional discomfort with intermittent aching pain in the shoulder that would come randomly and unpredictably. The patient stated he was still concerned because he was doing so well before his functional capacity evaluation (FCE) and after that he now had consistent problems and he felt like something pulled loose during that time. Rotator cuff weakness was present at 4/5. There was mild tenderness and slightly decreased ROM. Tone was significantly decreased. stated the patient had progressed well with his ROM; however, he still had significant weakness and difficulty with his rotator cuff. Because of his symptoms, the patient was determined to be unable to return to work. A magnetic resonance imaging (MRI) was ordered to better evaluate the soft tissue and bony structures and to make a more definitive diagnosis.

On April 3, 2015, a **MRI of the left shoulder** demonstrated a recurrent, full-thickness, full width tearing of the supraspinatus tendon and full-thickness tearing of the anterior half of the infraspinatus tendon with up to 30 mm of medial retraction of the torn tendon fibers; high grade articular side tearing of the superior half of the subscapularis tendon; mild supraspinatus muscle belly atrophy with grade ½ fatty infiltration throughout the rotator cuff musculature; interval long head biceps tenodesis with attenuation and longitudinal fissuring of the proximal tenodesed tendon; circumferential degenerative labral tearing; mild-to-moderate glenohumeral joint osteoarthritis with a small joint effusion.

On April 9, 2015, reviewed the MRI and interpreted it as showing significant atrophy throughout the supraspinatus and attenuation of the tendon with a recurrent tear. There was also significant retraction noted stated he did not feel the patient was a good candidate for revision rotator cuff repair as the tissue was very friable. However, conservative treatment should be continued and the patient was to perform activities as tolerated and try to avoid anything aggravating.

On April 27, 2015, the patient presented for a second opinion to regarding left shoulder pain/recurrent tear of the rotator cuff. It was noted the patient tripped over a hose and fell sustaining injury to the left shoulder. The patient stated he still had quite a bit of pain. He complained of weakness picking up the shoulder. The pain was now constant and described it like a toothache. Examination of the left shoulder showed significant muscular atrophy around the area of the supraspinatus and infraspinatus; 126 degrees of active forward elevation, 153 degrees of passive forward elevation, 140 degrees of external rotation and 145 degrees of abduction. Internal rotation was to T12. With the arm abducted at 90 degrees, the patient had almost normal extension and external rotation. The assessment was left shoulder pain, recurrent tear of the rotator cuff left shoulder, impingement syndrome left shoulder status post biceps tenodesis and paresthesias in the left arm/hand. explained to the patient that he did agree with that the chances of repair of the rotator cuff tear would be unlikely to have a good result. There was a low probability that the patient would be able to return to his previous job as an xxxxxx.

On May 21, 2015, noted the patient had really been taking it easy and was afraid to even use his left arm much for fear it will make his shoulder hurt worse. The patient continued to really have a lot of pain and problems. X-rays of the shoulder, three views, showed moderate arthritic change with moderate joint space narrowing and marginal osteophyte formation. The patient was explained that the best treatment was to consider a reverse shoulder arthroplasty given the traumatic arthropathy in the shoulder and the loss of rotator cuff function. Even with this, the patient would have some disability and may not be able to get back to all of his normal lifting and pushing and pulling.

On June 4, 2015, the patient stated he was still having limited ROM and was complaining of a tearing pain whenever raising his left arm. The pain would increase at night. He could actively elevate the arm and hold it against gravity only, but he had no strength beyond gravity. Passive ROM showed forward flexion of 180 degrees, abduction 80 degrees, active ROM is extremely limited with forward flexion 60 degrees, abduction 45 degrees. Per the request for reverse shoulder arthroplasty had been denied by Worker's Compensation.

On June 15, 2015, the request for left shoulder reverse arthroplasty was non-certified. Rationale: *"Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request is non-certified. The clinical documentation submitted for review did not provide information noting that the patient has a non-functioning, irreparable rotator cuff. Moreover, there was no documentation noting the recent failure of conservative care to include physical therapy."*

On July 2, 2015, in a follow-up with, the patient reported ongoing limited ROM and numbness in the arm at night. He was complaining of constant achy pain with difficulty sleeping and no improvement in symptoms. The patient could actively elevate the arm and hold it against gravity only, but he had no strength beyond gravity. Passive ROM showed forward flexion 180, abduction 80 degrees. Active ROM was extremely limited with forward flexion 60 and abduction 45 degrees following which the patient would use scapulothoracic motion to compensate. offered the patient a steroid injection for acute relief of his symptoms. The patient declined physical therapy (PT).

On August 6, 2015, the request for reconsideration of left shoulder reverse arthroplasty was non-authorized. Rationale: *"Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request is non-certified. There was no evidence in the medical reports submitted that the patient has exhausted conservative management including corticosteroid injections prior to the proposed surgery. There was also no clear indication of a failed hemiarthroplasty or total shoulder arthroplasty with irreparable rotator deficiency to warrant a reversed arthroplasty."*

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

This patient in the 8th decade of life has a failed rotator cuff repair, with substantial symptoms and clinical evidence of good ROM without severe weakness or any neurologic dysfunction. A reverse TSA is indicated. There is no reasonable expectation that this particular claimant will experience a favorable outcome with continued conservative management.

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

ODG: Reverse TSA:

Recommended as indicated below. Reverse shoulder arthroplasty is often used for people who have shoulder arthritis coupled with an irreparable rotator cuff tear, and it is also performed for patients with very complex shoulder problems, including those with failed previous surgical treatments. It is a newer type of shoulder replacement developed in Europe in the 1980s and approved by the FDA in 2004. It involves the insertion of a hemispherical implant in place of the glenoid instead of the humerus and the cup section being added to the humerus, allowing the arm to be moved primarily by the deltoid instead of the rotator cuff. Early results are encouraging, but not all shoulder surgeons have experience in reverse shoulder replacement. The reverse shoulder arthroplasty prosthesis was originally designed for rotator cuff arthropathy, and provided good results. Over time, the indications have expanded to include, among others, irreparable rotator cuff tears and rheumatoid arthritis, and the results have become more variable. There are also fundamental differences in the designs of the original Delta III prostheses and the later developed reverse shoulder prosthesis, and many studies that provide the results in reverse shoulder arthroplasties do not consider these 2 prostheses separately. ([Khan, 2011](#)) Reverse shoulder arthroplasty indications are steadily increasing in acute displaced proximal humeral fracture. Pain and articular movement results appear better than those with hemiarthroplasty. Healing rate was 37% in

hemiarthroplasty group compared to 84% in the reverse arthroplasty group, and the highest rate of complications was recorded in the hemiarthroplasty group. ([Baudi, 2014](#)) Displaced proximal humeral fractures have traditionally been treated with hemiarthroplasty in older adults, but sometimes hemiarthroplasty results in poor functional outcomes due to rotator cuff deficiency. Reverse shoulder arthroplasty (RSA) can offer potentially improved outcomes in these situations. RSA results in improved forward flexion and functional outcome scores compared with hemiarthroplasty for older adults with proximal humeral fractures. Complications following fracture do not appear to be appreciably higher in the RSA group. The results of this review suggest that RSA is a reasonable alternative for treating older adults with proximal humeral fractures, but more research and longer follow-up are needed. ([Mata-Fink, 2013](#)) See also [Arthroplasty](#) (shoulder); [Arthroscopic debridement](#) (for shoulder arthritis). For average hospital LOS if criteria are met, see [Hospital length of stay](#) (LOS).

Risk versus benefit: Overall complication rates were 25% (5% major) after primary RSA and 69% after revision RSA. ([Saltzman, 2014](#)) RSA compared with TSA patients, had significantly longer length of stay, higher hospital charges that are not completely attributable to increased implant costs alone, and increased rates of perioperative complications. ([Jiang, 2014](#)) Early RSA revision has been associated with age less than 65, smoking and obesity, with dislocation being the most common reason. ([Werner, 2015](#)) Young age, high pre-operative function, and neurologic dysfunction were associated with poor functional improvement after RSA for massive rotator cuff tears without arthritis. ([Hartzler, 2015](#)) Due to higher surgical risks for these more complex conditions, RSA should be carefully considered for strict indications only. Compared to other total joint arthroplasties there is reported to be a steep surgical learning curve as well as relatively poor revision options.

ODG Indications for Surgery™ -- Reverse Shoulder Arthroplasty:

- Non-functioning irreparable rotator cuff and gleno-humeral arthropathy; or
- Failed hemiarthroplasty or failed total shoulder arthroplasty with irreparable rotator deficiency; or
- Comminuted fractures (3 or 4 part) of the proximal humerus in an older population (65 years of age or older).
- And meet all of the following criteria:
 - Limited functional demands; &
 - Intractable pain that has not responded to conservative therapy (including NSAIDs, intra-articular steroid injections, and physical therapy for at least 6 months and failed); &
 - Adequate deltoid function; &
 - Adequate passive range of motion to obtain functional benefit from the prosthesis; &
 - Residual bone permits firm fixation of the implant; &
 - No evidence of shoulder infection; &
 - **No severe neurologic deficiency.**