Reverse Shoulder Arthroplasty

**Medical Policy**

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**Issue**
12/2013

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**Description**

Reverse shoulder arthroplasty uses a prosthesis that reverses the “ball-and-socket” configuration of the glenohumeral joint. With the reverse shoulder prosthesis, the spherical “ball” component is attached to the glenoid and the cup-shaped polyethylene “socket” is attached to the humerus.

Natural shoulder configuration requires a functioning rotator cuff to balance the anterior-superior pull of the deltoid muscle and stabilize the joint. In the absence of stabilization by the rotator cuff, deltoid muscle contraction may result in superior subluxation of the humeral head. Subsequently, use of conventional total shoulder prostheses in patients with a non-functioning rotator cuff frequently leads to long-term complications and unsatisfactory functional results. Hemiarthroplasty has largely replaced total shoulder arthroplasty for the treatment of patients with a non-functioning rotator cuff, but this procedure is associated with limited functional outcomes. For example, patients may be unable to lift the arm to shoulder level, and a “successful” hemiarthroplasty is typically based on “limited goals criteria.”

The reverse shoulder prosthesis (RSP) was specifically designed to address the limitations of conventional prostheses in patients with a non-functioning irreparable rotator cuff. Biomechanically, the RSP moves the center of rotation of the arm laterally and changes the direction of the pull of the deltoid muscle, allowing the deltoid to elevate the arm without functioning rotator cuff tendons. It is proposed that the RSP may provide a viable surgical solution for salvaging function in patients with irreparable non-functioning rotator cuffs. The primary indication is painful and symptomatic rotator-cuff tear arthropathy, characterized by superior subluxation of the humeral head in conjunction with glenohumeral arthrosis. Also being investigated are failed shoulder arthroplasty (total shoulder or hemiarthroplasty) where a non-functioning rotator cuff results in superior subluxation of the conventional prosthesis; rheumatoid arthritis where there is associated rotator-cuff arthropathy; and post-traumatic arthritis with rotator-cuff dysfunction. Implantation of the RSP is considered to be a technically challenging surgical procedure that may be associated with a high complication rate. Device-specific complications include notching of the inferior scapula, baseplate fixation failures, and dislocation of the prosthesis.
The first RSP (Delta) was developed in France in 1985; it is frequently described by the name of its designer as the Grammont reverse shoulder prosthesis. The redesigned Delta III prosthesis, marketed by DePuy, has been used in Europe since 1991. DePuy received marketing clearance for the Delta III Reverse Shoulder prosthesis in the United States through the U.S. Food and Drug Administration (FDA) 510(k) process in 2003 and for the Delta Xtend™ Reverse Shoulder System in 2007. The Tournier Aequalis Reverse Shoulder prosthesis received 510(k) clearance for marketing in 2004. The Trabecular Metal™ Reverse Shoulder System (Zimmer) and the Encore® Reverse® Shoulder Prosthesis (Encore Medical) received 510(k) marketing clearance in 2005. The SMR Modular Shoulder System (Systema Multipla Randelli, Italy) is not presently cleared for marketing in the U.S.

A number of device modifications and indications have been reviewed through the FDA’s 510(k) process. Representative indications (K052086) are “for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient’s joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. During primary surgery, after the humerus is prepared for the reverse SP humeral stem, if the glenoid bone stock appears “insufficient” to bear the load of the glenoid baseplate, a reverse SP humeral stem adapter can be used to convert the reverse SP humeral stem to a hemiarthroplasty prosthesis.”

**Policy**

Reverse shoulder arthroplasty may be considered **medically necessary** in patients with the following conditions when no alternative treatment would be expected to provide an acceptable clinical outcome:

- Failed hemiarthroplasty or failed total shoulder arthroplasty with irreparable rotator cuff deficiency;
- Fractures of the proximal humerus;
- Non-functioning irreparable rotator cuff and glenohumeral arthropathy.

Reverse shoulder arthroplasty is considered **investigational** for all other conditions.

**Policy Guidelines**

Patients should have adequate deltoid function and adequate passive range of motion (e.g., elevation of at least 90 degrees) to obtain a functional benefit from the prosthesis.

Due to the high complication rate associated with this procedure, implantation of the reverse shoulder prosthesis:

- Should be conducted by an experienced shoulder surgeon
- Should be used only in cases where the residual bone permits firm fixation of the implant
- May be converted to either total shoulder, or hemi-shoulder replacement (hemiarthroplasty), if the glenoid is fractured intraoperatively

There is no specific CPT code for reverse shoulder arthroplasty. The procedure is most likely coded using one of the following codes:
Rationale

Rotator cuff arthropathy is considered to be rare. Data from the National Center for Health Statistics indicates that, in total, about 23,000 shoulder replacement surgeries were performed in 2002. (1) The literature consists primarily of retrospective studies from Europe where the reverse shoulder prosthesis (RSP) has been in use the longest. No comparative trials of reverse shoulder arthroplasty were identified in the literature review. Therefore, to compare patient outcomes with an established surgical procedure, results from hemiarthroplasty in patients with rotator cuff arthropathy were also reviewed. (2)

Literature Review

Hemiarthroplasty

In general, hemiarthroplasty results (Table 1) are consistent with the “limited goals criteria” attributed to Neer, with a reduction in pain but limited postoperative range of motion (ROM). (3) For example, a retrospective review of 34 patients (37 shoulders) who had undergone hemiarthroplasty for glenohumeral arthritis and irreparable rotator cuff deficiency showed a 19 degree improvement in elevation (72 degrees preoperatively to 91 degrees postoperatively). (4) Pain improved from a score of 4.2 to 2.2 on a 5-point scale at an average 5 years of follow-up (range, 2–11 years), with 9 (27%) patients reporting moderate pain. Moderate-to-severe superior subluxation was observed in 32 shoulders immediately postoperatively; 30 cases of progressive erosion or fracture of the glenoid or acromion were observed radiographically at an average of 3 years. Eight (22%) shoulders showed notching of the medial aspect of the humerus.

Another retrospective review assessed the relation between preoperative factors and improvements in shoulder function after humeral hemiarthroplasty in 68 patients (71 shoulders). (5) Using a self-assessment questionnaire mailed at least 24 months after surgery (up to 142 months), the study found that patients with an intact rotator cuff (n =41) had the ability to perform an average of 3.4 simple shoulder functions (of 12) before surgery and 7.0 functions after surgery. In comparison, patients with a cuff tear (n =30) improved from a pre-operative scale of 2.9 to 5.1 after surgery. Differences in function between patients with a cuff tear and those with an intact rotator cuff were primarily in the ability to lift the arm (with or without weight) to the level of the shoulder.

Another study reported 4-year follow-up (range, 2–12 years) following hemiarthroplasty in a consecutive series of 40 shoulders with severe rotator cuff deficiency. (6) Five patients died and 1 was lost to follow-up, resulting in 34 shoulders (31 patients) treated by hemiarthroplasty and attempted rotator cuff repair. Twenty-six of the 34 shoulders (76%) were reported to have satisfied the limited goals criteria, meaning that the patient had no or mild pain, was pleased with the outcome of the procedure, and was capable of independent self-care (i.e., able to dress, place their hand to their mouth for eating, lie on the affected side, and comb their hair). Long-term follow-up was available for 25 of the 34 shoulders (74%), with a mean American Shoulder and Elbow Surgeons system (ASES) score of 67 of 100 points. The greatest predictor of outcome was the ability to actively elevate the arm to 90 degrees or greater preoperatively, with a significant difference between the two groups (i.e., elevation < 90 degrees vs. elevation of at least 90 degrees) for total ASES scores (80 vs. 54) as well as the component function (31 vs. 23) and pain relief (48 vs. 30 points) subscores. For the subgroup of shoulders in which only
partial coverage of the humeral head was achieved (n = 22), active forward elevation improved from 63 degrees at baseline to 103 degrees at follow-up. Limited goals criteria were achieved in 16 (73%) of the patients in this subgroup.

Table 1. Range of motion (ROM) following hemiarthroplasty in patients with irreparable rotator cuff deficiency/cuff tear arthrosis (CTA)

<table>
<thead>
<tr>
<th>Study</th>
<th>% of total N</th>
<th>Patients with CTA</th>
<th>Baseline ROM</th>
<th>Post-tx ROM</th>
</tr>
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<tbody>
<tr>
<td>Goldberg et al 2008(6)</td>
<td>64</td>
<td>22</td>
<td>63°</td>
<td>103°</td>
</tr>
<tr>
<td>Hettrich et al 2004 (5)</td>
<td>40</td>
<td>30</td>
<td>…</td>
<td>&lt; 90°</td>
</tr>
<tr>
<td>Sanchez-Sotelo et al 2001 (4)</td>
<td>100</td>
<td>33</td>
<td>72°</td>
<td>91°</td>
</tr>
</tbody>
</table>

Table 2. Range of motion (ROM) following reverse shoulder arthroplasty in patients with irreparable rotator cuff deficiency/cuff tear arthrosis (CTA)

<table>
<thead>
<tr>
<th>Study</th>
<th>% of total N</th>
<th>Patients with CTA</th>
<th>Baseline ROM</th>
<th>Post-tx ROM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boileau et al 2006 (10)</td>
<td>47</td>
<td>21</td>
<td>52°</td>
<td>123°</td>
</tr>
<tr>
<td>Frankle et al 2005 (11)</td>
<td>100</td>
<td>60</td>
<td>55°</td>
<td>105°</td>
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<tr>
<td>Sirveaux et al 2004 (7)</td>
<td>100</td>
<td>80</td>
<td>73°</td>
<td>138°</td>
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<td>Wall et al 2007 (9)</td>
<td>14</td>
<td>34</td>
<td>94°</td>
<td>143°</td>
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<tr>
<td>Werner et al 2005 (14)</td>
<td>100</td>
<td>50</td>
<td>42°</td>
<td>100°</td>
</tr>
</tbody>
</table>

Table 3. Pain and function measured by the Constant score or the American Shoulder and Elbow Surgeons system (ASES) following reverse shoulder arthroplasty in patients with irreparable rotator cuff deficiency/cuff tear arthrosis (CTA)

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Measure</th>
<th>Follow-up, mo [range]</th>
<th>Baseline</th>
<th>Post-tx</th>
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<tr>
<td>Boileau et al 2006 (10)</td>
<td>21</td>
<td>Constant score</td>
<td>40 [24-72]</td>
<td>18</td>
<td>66</td>
</tr>
<tr>
<td>Frankle et al 2005 (11)</td>
<td>60</td>
<td>ASES</td>
<td>≥ 24 [24-68]</td>
<td>34</td>
<td>68</td>
</tr>
<tr>
<td>Sirveaux et al 2004 (7)</td>
<td>80</td>
<td>Constant score</td>
<td>44 [24-97]</td>
<td>23</td>
<td>66</td>
</tr>
<tr>
<td>Wall et al 2007 (9)</td>
<td>34</td>
<td>Constant score</td>
<td>40 [24-118]</td>
<td>28</td>
<td>63</td>
</tr>
<tr>
<td>Werner et al 2005 (14)</td>
<td>50</td>
<td>Constant score</td>
<td>38 [24 or more]</td>
<td>29</td>
<td>64</td>
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Reverse Shoulder Arthroplasty

Grammont (Delta) Reverse Shoulder Prosthesis

The majority of publications on reverse shoulder arthroplasty are retrospective cohort studies from Europe (Tables 2 and 3). Intermediate term follow-up was reported from a multicenter study of 92 consecutive cases performed between 1991 and 1999. (7) Six patients were lost to follow-up and 6 patients died with the prosthesis in place, resulting in follow-up from 80 (87%) procedures in 77 patients at an average 44 months (range of 24–97 months). Kaplan-Meier survivorship analysis (30 patients at 24 to 36 months’ follow-up, 30 from 36 to 60 months, and 17 at over 60 months) indicated 95% prosthesis survival at 97 months. With failure defined as revision, component failure, or significant pain, survivorship of the prosthesis was 88% at 5 years, 72% at 7 years, and 29% at 8 years. A 2006 publication reported on 80 of the 92 shoulders included in the 2004 analysis, describing 66 patients with glenohumeral arthritis and irreparable cuff deficiency and 14 cases of other etiologies. (8) Eighteen patients had died and results were reported for 57 patients (71% of 80, or 62% of the original group of 92) at an average follow-up of 70 months (range of 60–121 months). Prosthesis survival was calculated for patients with cuff tear versus other etiologies. Survival was estimated to be 95% at 10 years for cuff tear and 77% for other etiologies; glenoid loosening was 91% and 77%, respectively.

Survival analysis for pain was reported to be 81%–88% at 6 years and 58%–61% at 10 years for both groups. Although these results appear favorable, discrepancies in subject numbers and outcomes between the 2 publications raise questions about reporting.

Wall et al published results from 240 consecutive reverse shoulder arthroplasties in 232 patients; 186 (82%) of the patients were followed up for an average of 40 months. (9) Overall, the Constant score improved from 23 points before surgery to 60 points at follow-up. Elevation improved from 86 degrees to 137 degrees. When results were analyzed by etiology, patients with primary rotator cuff tear arthropathy (n = 59; Constant score 65; elevation of 142 degrees), primary osteoarthritis with a rotator cuff tear (n = 25; Constant score 65; elevation of 115 degrees), or a massive rotator cuff tear without arthritis (n = 34; Constant score 63; elevation of 143 degrees) had better outcomes in comparison with patients in the posttraumatic arthritis (n = 28; Constant score 53, elevation of 115 degrees) and revision arthroplasty groups (n = 45; Constant score 52; elevation of 118 degrees). Complications were observed in 36 (19%) patients; the risk of complication for revision surgery (37%) was greater than for primary surgery (13%). Another group from France reported 40-month follow-up (range, 24–72 months) on 45 patients with irreparable cuff tear (n = 21), fracture sequelae (n = 5), or revision surgery after a failed prior arthroplasty (n = 19). (10) Overall, the Constant score improved from 17 points before surgery to 58 points at follow-up; the improvement was significantly greater in the group of patients with cuff tear arthropathy compared with the patients who had revision surgery (66 vs. 46). Overall, elevation improved from 55 to 121 degrees (123 degrees for CTA and 113 degrees for revision surgery), and 67% of the patients reported having no or slight pain.

Scapular notching was observed in 24 (68%) of cases, with the notch extending beyond the inferior screw in 28% of cases. No glenoid loosening was observed at the time of follow-up. Klein et al. conducted a prospective study of the Delta III prosthesis in 20 patients (67 to 85 years of age) with comminuted fractures of the proximal humerus. (11) Follow-up at an average of 33 months (range 24-52 months) showed anterior elevation of 122 degrees (range 60-175). The Constant Score was 68 (range 47-98) and the American Shoulder and Elbow Surgeon (ASES) score was 68 (50-90). Radiographic analysis showed no evidence of base plate or humeral stem loosening, and no osteolysis or migration of the stem. One patient had Nerot grade I signs of inferior notching. One patient had 2 dislocations of the prosthesis; these were reduced under general anesthesia and no reoperation was necessary.
In addition to complications such as infection and nerve damage that are related to any complex shoulder reconstruction, baseplate fixation failures and dislocation of the prosthesis have been reported. (12) The highest complication rate (including minor complications) and reoperation rate (50% and 33%, respectively), were reported by Werner et al in patients undergoing either initial or revision surgery for painful pseudoparesis (defined as active shoulder elevation of < 90 degrees in the presence of free passive anterior elevation); for the subgroup of patients undergoing initial surgery with an RSP the reoperation rate was 18%. (12, 13) The most common complication after implantation of the Delta III prosthesis is notching of the inferior scapula, which is believed to be caused by contact with the humeral component. Notching may be confined or extend under the screws and baseplate.

**Encore Reverse Shoulder Prosthesis**

A U.S. group published industry-sponsored reports on the Encore Reverse Shoulder Prosthesis. One study provided at least a 2-year follow-up on 60 patients (average age, 71 years; range, 34 to 86 years) who had received a RSP for severe rotator cuff deficiency. (14) All patients had previously undergone unsuccessful nonoperative and operative treatment of the rotator cuff and demonstrated subluxation of the humeral head as well as erosion of the glenohumeral joint. Exclusion criteria were active infection, axillary nerve palsy, a nonfunctioning deltoid muscle, insufficient bone to seat the implant components, or a very high level of physical activity. At a minimum of 2 years of follow-up (24 to 68 months), the total ASES score had improved from 34 to 68, with significant improvements in both pain (ASES, from 18 at baseline to 38 at follow-up; visual analog scale [VAS], 6.3 to 2.2) and function (ASES, 16 to 29; VAS, 2.7 to 6.0). Forward flexion improved from 55 degrees at baseline to 105 degrees at follow-up. Independent evaluation of the postoperative radiographs indicated no evidence of progressing subluxation, erosion, or notching. Complications were reported in 10 (17%) patients, with 7 (12%) failures requiring revision to either hemiarthroplasty (n = 2) or another RSP (n = 5). Results were considered to be good or excellent for 41 (68%) patients with glenohumeral arthritis and severe rotator cuff deficiency, and satisfactory for 16 (27%).

Another report from this group described follow-up of at least 2 years in 29 of 57 (51%) patients treated with an RSP for failed hemiarthroplasty following proximal humeral fracture. (15) The ASES improved from 22 to 52, with improvement of the pain subscore from 12 to 34. The function score improved by only 8 points (10 to 18; p = 0.06). Abduction improved 36 degrees (from 34 to 70 degrees). The overall complication rate was 28%, with hardware failure observed in 14% of cases. A third publication reported 2-year results with a modified surgical technique (inferior tilt of the glenosphere) and larger (5.0 mm) locking screws for the baseplate in 112 patients (114 shoulders) with rotator cuff deficiency of the shoulder along with glenohumeral subluxation, glenohumeral arthritis, or pseudoparesis. (16) Ninety-four patients (84%) were available for follow-up, including 37 shoulders with primary rotator cuff deficiency, 33 with a previous rotator cuff operation, 23 with a previous arthroplasty, and 3 with a proximal humeral nonunion. The number of patients with irreparable rotator cuff deficiency was not indicated. The average ASES score improved from 30 to 78. Patients with primary cuff deficiency achieved better results (ASES of 86) in comparison with those who had failed arthroplasty (ASES of 68). Blinded analysis of videotapes by an independent reviewer showed improved range of motion. For example, forward elevation improved from 74 to 130 degrees in patients with primary cuff deficiency, and from 46 to 90 degrees in patients with failed arthroplasty. Nine complications (9%) were observed; the most frequent was dislocation due to instability or falls. The low complication rate in this series may be related to the high volume experience of the surgeon, who is also the designer of the Encore implant.

**Tornier Aequalis Reverse Shoulder Prosthesis**
A prospective evaluation was performed on 138 consecutive reverse arthroplasties performed with a deltopectoral approach to evaluate the relation between subscapularis insufficiency and dislocation. (17) The subscapularis tendon was reparable in 62 patients and irreparable in 76 at the conclusion of the procedure. Seven postoperative dislocations occurred; all dislocations were in patients whose subscapularis was irreparable. No postoperative dislocations occurred in patients with rotator cuff tear arthropathy or rheumatoid arthritis. The risk of dislocation with an irreparable subscapularis tendon following a deltopectoral approach was estimated at almost twice that of patients with a repaired subscapularis tendon.

Wierks et al. conducted a retrospective review to assess the learning curve and complications in the first 20 patients implanted with a RSP (4 DePuy and 16 Tornier). (18) Difficulties early in the series included keeping the guide in place and fractures of the glenoid from the high torque of a pneumatic power drill. The complication rate of 75% was significantly higher than the mean complication rate of 25% (14% to 36%) reported in 12 published articles. At a mean 9 months’ follow-up (range of 3-21 months) scapular notching (Grade 1 to Grade 3) was present in 11 patients (55%); heterotopic ossification was observed in 9 patients (45%). There was no radiographic evidence of fracture or component loosening, dissociation, or dislodgement, and the intraoperative fractures appeared to be healed or healing.

SMR Modular Shoulder System
The first publication on the SMR prosthesis (which does not have FDA clearance) was reported by Young and colleagues in 55 consecutive patients (56 shoulders). (19) The glenoid component of this prosthesis has a curved backing, hydroxyapatite coating, a large tapered central peg and the possibility of inserting the screws at variable angles; all of these features are aimed at improving glenoid fixation. At an average 38-month follow-up on 49 shoulders (87% follow-up; 5 patients had died and 1 had moved overseas), 92% of patients reported no or minimal pain with a visual analog scale score. The average anterior elevation was 122°. There were 3 complications from the surgery and 1 postoperative dislocation that was reduced under general anesthesia. Inferior scapular notching (less than 5 mm) was observed in 12 patients (25%). There was no evidence of glenoid loosening and no reoperations were needed at the early follow-up.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received from 3 academic medical centers while this policy was under review in 2008; however, no input was received from physician specialty societies. While the various Physician Specialty Societies and Academic Medical Centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the Physician Specialty Societies or Academic Medical Centers, unless otherwise noted. All three reviewers supported use of the reverse shoulder prosthesis for patients with irreparable rotator cuff arthropathy, when no alternative treatment would be expected to provide an acceptable clinical outcome, as adopted into the policy in August 2008.

Summary
Overall, the literature suggests that shoulder function (specifically ROM for forward elevation) may be improved in comparison with the “limited goals” expected following hemiarthroplasty in a select group of patients. However, complications with this type of prosthesis are common, and the long-term survival of the implants is currently unknown. The majority of investigators appear to agree with the statement that “because of the high complication rate and the fact that there may be long-term complications that are not yet known, arthroplasty with this implant should be reserved as a salvage procedure for situations in which an acceptable clinical outcome cannot be expected with another treatment modality.” (14)
It should be noted that implant designs are continuing to evolve. At the present time, the available evidence from retrospective uncontrolled trials indicates that use of the RSP in patients with rotator cuff deficiency may result in improved shoulder function in comparison with hemiarthroplasty. Short-term outcomes also appear adequate for salvage situations such as failed shoulder arthroplasty and complicated fractures of the humerus. The improvement in short-term and intermediate outcomes must, however, be balanced against a higher complication rate and uncertainty regarding long-term outcomes. This evidence is considered sufficient for patients to make an informed choice based on assessment of comparative risks and benefits. Thus, reverse shoulder arthroplasty is considered to be an appropriate salvage procedure when no alternative treatment is available that would be expected to result in an acceptable clinical outcome.

References:


Codes

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