Name of Policy: Reverse Shoulder Arthroplasty

Policy #: 327
Category: Surgery
Latest Review Date: August 2010
Policy Grade: Effective 02/06/2013: Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Reverse shoulder arthroplasty is conducted with a prosthesis that reverses the “ball-and-socket” configuration of the glenohumeral joint. With the reverse shoulder prosthesis (RSP), 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 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 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-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. (See Approved by Governing Bodies for appropriate use of devices)

**Policy:**
**Effective for dates of service on or after August 1, 2010:**
Reverse shoulder arthroplasty meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage 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; or
- Comminuted fractures (3 or 4 part) of the proximal humerus in an older population (e.g., 65 years of age or older); or
- Non-functioning irreparable rotator cuff and glenohumeral arthropathy

Patients should have adequate deltoid function and adequate passive range of motion to obtain a functional benefit from the prosthesis.
Reverse shoulder arthroplasty does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational for all other conditions.

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

Effective for dates of service from August 2008 through July 31, 2010:

Reverse shoulder arthroplasty meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in patients with a failed Hemiarthroplasty or failed total shoulder arthroplasty with irreparable rotator cuff deficiency, when no alternative treatment would be expected to provide an acceptable clinical outcome.

Reverse shoulder arthroplasty meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in patients with a non-functioning irreparable rotator cuff and glenohumeral arthropathy, when no alternative treatment would be expected to provide an acceptable clinical outcome. Patients should have adequate deltoid function and adequate passive range of motion to obtain a functional benefit from the prosthesis.

Reverse shoulder arthroplasty does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational for all other conditions.

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

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.
Key Points:
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. The literature consists primarily of retrospective studies from Europe where the reverse shoulder prosthesis has been the longest in use. No comparative trials of reverse shoulder arthroplasty were identified in the literature review. Therefore, in order to compare patient outcomes with an established surgical procedure, results from Hemiarthroplasty in patients with rotator cuff arthropathy were also reviewed.

Hemiarthroplasty
Generally, Hemiarthroplasty results (Table 1) are consistent with the “limited goals criteria” attributed to Neer, with a reduction in pain but limited post-operative range of motion (ROM). For example, a retrospective review of 34 patients (37 shoulders) who had undergone Hemiarthroplasty for glenohumeral arthritis and irreparable rotator cuff deficiency showed a 19º improvement in elevation (72º preoperatively to 91º postoperatively). Pain improved from a score of 4.2 to 2.2 on a 5 point scale at an average 5 years follow-up (range of 2-11 years), with 9 (27%) patients reporting moderate pain. Moderate-to-severe superior subluxation was observed in 32 shoulders immediately post-operatively; 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 medical 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). 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 (out 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 the 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 of 2 to 12 years) following Hemiarthroplasty in a consecutive series of 40 shoulders with severe rotator cuff deficiency. 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 points out of 100. 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) sub-scores. For the subgroup of shoulders in which only partial coverage of the humeral head was achieved (n = 22), active forward elevation improved from 63º
at baseline to 103° 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>
</thead>
<tbody>
<tr>
<td>Goldberg et al 2008</td>
<td>64%</td>
<td>22</td>
<td>63°</td>
<td>103°</td>
</tr>
<tr>
<td>Hettrich et al 2004</td>
<td>40%</td>
<td>30</td>
<td>&lt;90°</td>
<td></td>
</tr>
<tr>
<td>Sanchez-Sotelo et al 2001</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</td>
<td>47%</td>
<td>21</td>
<td>52°</td>
<td>123°</td>
</tr>
<tr>
<td>Frankle et al 2005</td>
<td>100%</td>
<td>60</td>
<td>55°</td>
<td>105°</td>
</tr>
<tr>
<td>Sirveaux et al 2004</td>
<td>100%</td>
<td>80</td>
<td>73°</td>
<td>138°</td>
</tr>
<tr>
<td>Wall et al 2007</td>
<td>14%</td>
<td>34</td>
<td>94°</td>
<td>143°</td>
</tr>
<tr>
<td>Werner et al 2005</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 [range]</th>
<th>Baseline</th>
<th>Post-tx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boileau et al 2006</td>
<td>21</td>
<td>Constant score</td>
<td>40 months [24-72]</td>
<td>18</td>
<td>66</td>
</tr>
<tr>
<td>Frankle et al 2005</td>
<td>60</td>
<td>ASES</td>
<td>&gt;/= 24 months [24-68]</td>
<td>34</td>
<td>68</td>
</tr>
<tr>
<td>Sirveaux et al 2004</td>
<td>80</td>
<td>Constant score</td>
<td>44 months [24-97]</td>
<td>23</td>
<td>66</td>
</tr>
<tr>
<td>Wall et al 2007</td>
<td>34</td>
<td>Constant score</td>
<td>40 months [24-118]</td>
<td>28</td>
<td>63</td>
</tr>
</tbody>
</table>

**Reverse Shoulder Arthroplasty**

*Grammont (Delta Reverse Shoulder Arthroplasty)*

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 multi-center study of 92 consecutive cases performed between 1991 and 1999. 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. 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 vs. 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 for an average of 40 months. Overall, the Constant score improved from 23 points before surgery to 60 points at follow-up. Elevation improved from 86º to 137º. When results were analyzed by etiology, patients with primary rotator cuff tear arthropathy (n = 59; Constant score 65; elevation of 142º), primary osteoarthritis with a rotator cuff tear (n = 25; Constant score 65; elevation of 115º), or a massive rotator cuff tear without arthritis (n = 34; Constant score 63; elevation of 143º) had better outcomes in comparison with patients in the posttraumatic arthritis (n = 28; Constant score 53, elevation of 115º) and revision arthroplasty groups (n = 45; Constant score 52; elevation of 118º).

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 of 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). 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 55º to 121º (123º for CTA and 113º 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.

Encore Reverse Shoulder Prosthesis

A U.S. group published industry-sponsored reports on the Encore Reverse shoulder Prosthesis. One study provide at least 2 year follow-up on 60 patients (average age of 71 years, range 34 to 86 years) who had received a reverse shoulder prosthesis for severe rotator cuff deficiency. All patients had previously undergone unsuccessful non-operative 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 non-functioning deltoid muscle, insufficient bone to seat the implant components, or a very high level of physical activity. At a minimum of 2 years follow-up (24 to 68 months) the total American Shoulder and Elbow Surgeon (ASES) score had improved from 34 to 68, with significant improvements in both pain (ASES, from 18 at baseline to 38 at follow-up; 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 post-operative 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 reverse shoulder prosthesis (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. 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 36º (from 34º to 70º). 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. 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 non-union. 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 74º to 130º in patients with primary cuff deficiency, and from 46º to 90º 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.

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. 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 < 90º in the presence of free passive anterior elevation); for the subgroup of patients undergoing initial surgery with an RSP the reoperation rate was 18%. 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.

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 prosthesis are common, and the long-term survival of the implant 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”.

August 2010 Update
Grammont (Delta) Reverse Shoulder Prosthesis
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. 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 dislocations of the prosthesis have been reported. 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° in the presence of free passive anterior elevation); for the subgroup of patients undergoing initial surgery with an RSP the reoperation rate was 18%. 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.

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. 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). 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). 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 VAS score. The average anterior elevation was 122 degrees. There were 3 complications from the surgery and 1 postoperative dislocation that was reduced after the patient was placed 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.
In response to requests by the Blue Cross Blue Shield Association, 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.”

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.

**Key Words:**
Reverse shoulder arthroplasty, reverse shoulder prosthesis, Grammont prosthesis, comminuted fracture of the humerus

**Approved by Governing Bodies:**
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, marketing by DePuy, has been used in Europe since 1991.
DePuy received marketing clearance for the Delta III Reverse Shoulder prosthesis in the US through the 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.

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.

Biomet Comprehensive Reverse Shoulder received FDA approval on July 7, 2008

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
AT&T contracts: No special consideration
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Wal-Mart: Special benefit consideration may apply. Refer to member’s benefit plan.
Pre-certification requirements: Not applicable

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

- 23472 Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (e.g., total shoulder)
- 23929 Unlisted procedure, shoulder

ICD-9 Procedure Codes:
- 81.88 Reverse total shoulder replacement (effective 10/01/10)
References:

Policy History:
Medical Policy Group, August 2008 (3)
Medical Policy Administration Committee, September 2008
Available for comment September 5-October 20, 2008
Medical Policy Group, August 2010 (1) Updated Key Points, moved FDA info under Approved by Governing Bodies, added coverage for comminuted fractures of proximal humerus
Medical Policy Administration Committee, August 2010
Available for comment August 6-September 18, 2010
Medical Policy Group, February 2013:

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.