**Name of Policy:**
Shoulder Resurfacing

Policy #: 366
Category: Surgery

Latest Review Date: November 2010
Policy Grade: **Active policy but no longer scheduled for regular literature reviews and update.**

**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:**
Resurfacing the shoulder joint is a method to treat painful shoulders without replacing the humeral head. Humeral resurfacing can be conducted together with or without resurfacing of the glenoid. This policy addresses partial or complete resurfacing of the humerus, and resurfacing of both the humerus and glenoid.

Resurfacing of the humeral head can be accomplished with devices that provide either complete or partial coverage, and may be performed alone (hemi-resurfacing: HR) or in combination with glenoid resurfacing (total shoulder resurfacing: TSR). With TSR, the glenoid is resurfaced with similar implants and procedures as are currently used for total shoulder arthroplasty. Biologic resurfacing of the glenoid with meniscal allograft or other biologic tissue has also been reported, but is outside of the scope of the present policy.

The objective of resurfacing is to preserve the individual patient’s normal head-neck anatomy and bone stock. Prostheses that are used to resurface the humeral head differ from those traditionally used in hemi- or total shoulder arthroplasty by using a small peg that is impact fit through the humeral head/neck in place of a long stem inserted through the bone shaft. The prosthesis is implanted at the angle of the humeral neck instead of replacing the humeral head and neck. It has been proposed that in addition to reducing intraoperative blood loss and the occurrence of humeral periprosthetic fractures, resurfacing arthroplasty may avoid technical errors in version, head height, offset, and neck-shaft angle. It has also been proposed that resurfacing will improve revisions, since removal of stemmed implants are associated with tuberosity and shaft fractures that can lead to implant instability, proximal humerus bone loss, and poor shoulder function. In addition, the larger head size may lead to improved clinical outcomes. This policy therefore focuses on the impact of these design changes on clinical outcomes related to pain and function, as well as the long-term effects of resurfacing related to implant stability and durability in comparison with total shoulder or hemiarthroplasty.

Several prosthetic designs are currently available in the US. Developed by Copeland and colleagues, the Mark prosthesis is currently in its 3rd generation in Europe. The Copeland™ Mark 1 had a central pegged humeral component which was secured with a screw, and a polyethylene glenoid element that was stabilized by a peg. The Mark-2 prosthesis, which was introduced in 1990 in Europe, added a metal backing to the glenoid component and a fluted tapered peg to both components. The Mark-3 model, used since 1993, has a hydroxyapatite coating to improve bone ingrowth. Three sizes of the prosthesis are available. Copeland™ Extended Articulating Surface (EAS)™ Resurfacing Heads (Biomet Manufacturing) were cleared by the US Food and Drug Administration (FDA) through the 510(k) process in 2005. They are indicated for “hemi- or total shoulder replacement in patients with massive, irreparable rotator cuff tears and arthritis. Specific indications include cuff tear arthropathy and difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.” The glenoid component may be used for total shoulder resurfacing (both humerus and glenoid resurfaced) or total shoulder arthroplasty (humeral head replacement with glenoid resurfacing). The DePuy Global CAP™ CTA Resurfacing Shoulder Humeral Head (DePuy), cleared for marketing by the FDA in 2008, has the same indications as the Copeland device and lists an earlier model of the DePuy Global CAP and the Copeland EAS among predicate devices. The Axiom Shoulder Resurfacing System (Axiom Orthopaedics) was cleared for marketing by
the FDA in 2006 for use as a replacement of shoulder joints disabled by rheumatoid arthritis with pain; non-inflammatory degenerative joint disease (i.e., osteoarthritis and avascular necrosis); correction of functional deformity; fractures of the humeral head; traumatic arthritis. The Durom® cup (Zimmer, Switzerland) and the EPOCA RH Cup (Argo Medical, Switzerland) have not received clearance for marketing in the US.

A partial resurfacing implant for the shoulder, known as the HemiCAP® (Arthrosurface), was cleared for marketing in 2003 under the name Contoured Articular Prosthetic (CAP) Humeral Head Resurfacing Prosthesis (STD Manufacturing).

**Policy:**

Shoulder resurfacing, including total, hemi, or partial resurfacing, does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage is considered **investigational**.

*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:**

For the Copeland prosthesis, 6 case series and one matched-pair analysis were identified. Three of the 7 studies were published by the developers of the Copeland prosthesis with likely overlap in patients; some of whom underwent total shoulder resurfacing (TSR) and some hemi-resurfacing (HR). Three additional case series using 3 different prosthetic designs were also identified. The largest prospective and/or consecutive series are described below.

The appropriate comparison for shoulder resurfacing would be either total shoulder arthroplasty or hemiarthroplasty, depending on whether the glenoid was resurfaced or not. Therefore, comparative outcome studies of total shoulder arthroplasty and hemiarthroplasty are also described below.

**Total Shoulder Arthroplasty and Hemiarthroplasty**

Bryant, et al (2005), conducted a meta-analysis of 4 randomized trials that compared total shoulder arthroplasty with humeral head replacement or hemiarthroplasty. Included were 112 patients with an average age of 68 years. Two-year follow-up showed an advantage of total shoulder arthroplasty over hemiarthroplasty for pain and function on the UCLA scoring system. The score for function at 2 years was 8.1 in the total shoulder arthroplasty group and 6.6 in the hemiarthroplasty group. There was no evidence of heterogeneity between studies for this domain. Forward elevation was improved by 13 degrees for the total shoulder vs. hemiarthroplasty groups. Pain scores also favored total shoulder arthroplasty (8.6 vs. 6.5), although the heterogeneity among the studies decreased confidence in this result. The authors
noted the uncertainty in the longer-term effects of erosion of the glenoid (with hemiarthroplasty) compared with loosening of the glenoid component (with total shoulder arthroplasty), concluding that longer follow-up was needed.

Radnay, et al (2007), conducted a systematic review of 23 studies, primarily case series, describing outcomes from patients (n = 1952) treated with either total shoulder arthroplasty or humeral head replacement between 1966 and 2004. Patients treated with total shoulder arthroplasty were slightly older than those treated with hemiarthroplasty (average 66 vs 63 years of age). The mean follow-up was 43 months, with a range of 30 to 116 months. Analysis showed an advantage of total shoulder arthroplasty over hemiarthroplasty for pain and function. For the 14 studies (1185 patients) that included pain as an outcome measure, postoperative pain scores were significantly improved for shoulders undergoing glenoid resurfacing (mean of 86) compared with those undergoing isolated hemiarthroplasty (mean of 78). Patients who underwent total shoulder arthroplasty outperformed those who underwent hemiarthroplasty in forward elevation (141 degrees vs. 125 degrees) and external rotation (35 degrees vs. 25 degrees). The number of revisions was significantly lower for total shoulder arthroplasty over hemiarthroplasty (6.5% vs 10.2%) and 8.1% of the hemiarthroplasties were converted to total shoulder arthroplasty within the follow-up period. Revisions for all-polyethylene glenoid components (1.7%) were lower than for the metal-backed glenoid components (6.8%). These authors (along with a number of others) noted that the choice between total shoulder arthroplasty and hemiarthroplasty for the treatment of end-stage primary glenohumeral osteoarthritis remains controversial, due to uncertainty in long-term effects on the glenoid.

**Shoulder Resurfacing**

**Copeland Mark-1, 2, or 3 Prosthesis**

In 2001, Levy and Copeland published outcomes from a consecutive series of 103 prostheses in 94 patients treated between 1990 and 1994 with the Copeland Mark-2 prosthesis. Out of the series, 1 patient died less than 24 months after shoulder replacement and 4 patients were lost to follow-up, resulting in review of 98 shoulders. Sixty-eight shoulders also received a glenoid component for TSR while 35 received only the humeral component. Included were patients with osteoarthritis, rheumatoid arthritis, avascular necrosis, instability arthropathy, and post-traumatic arthropathy. The average age was 64 years (range of 22 to 88). About 20% of patients had irreparable or incompletely repaired cuff tear arthropathy. Independent assessment showed an improvement in the Constant score from 15 (age-adjusted of 24%) at baseline to 52 (75%) at an average 6.8 years after resurfacing (range, 5-10 years). The best results were observed in patients with primary osteoarthritis and TSR with a Constant score of 94%. Humeral resurfacing (HR) alone in this population resulted in a Constant score of 74%. Shoulders with cuff arthropathy or instability arthropathy had Constant scores of 61% and 63%, respectively. Radiological review on 88 humeral implants showed no evidence of radiolucency in 69%, a lucent line less than 1 mm in 28% and a progressive lucent line more than 2 mm in 2 shoulders. Eight shoulders were revised, 5 of which were revised to a stemmed humeral component. Mild subluxation of the humeral head was observed in 15 shoulders, moderate superior migration was observed in 7, and severe superior subluxation with obliteration of the acromiohumeral interval was observed in 8. Subluxation of the prosthesis was associated with cuff tear arthropathy. Additional reports from this group are retrospective reviews of patients with osteoarthritis or
rheumatoid arthritis treated between 1986 and 1998 with Copeland Mark-1, Mark-2, or Mark-3 prostheses. Overlap in patients between these publications is likely.

Thomas, et al (2005), a group from England, reported outcomes from a consecutive series of 52 patients (56 shoulders) who received humeral resurfacing with the Copeland Mark-3 prosthesis. Six patients died of other causes and 2 were lost to follow-up, resulting in an average 34-month assessment (range 24-63 months) of 44 patients (48 shoulders). Nine shoulders were followed for more than 4 years. The primary diagnosis was osteoarthritis in 20 patients, rheumatoid arthritis in 26, post-traumatic arthritis in one and rotator cuff arthropathy in one. The average age was 70 years (range 34-84). Independent post-operative assessment showed an improvement from 16 to 54 in the Constant score. One patient converted to total shoulder arthroplasty, 3 were revised for impingement and one patient had a fracture, resulting in an estimated 98% implant survival at 4 years (92% survival for any revision). Buchner, et al (2008), a German group of surgeon-investigators, reported a matched pair analysis comparing 22 patients who underwent resurfacing with the Copeland Mark-3 prosthesis with 22 matched patients who had received total shoulder arthroplasty in the same year. At 12-month follow-up, total shoulder arthroplasty resulted in greater improvement in the Constant score (from 26 at baseline to 67 at follow-up) in comparison with humeral resurfacing alone (from 33 at baseline to 59 at follow-up). Two of the patients who underwent humeral resurfacing converted to total shoulder arthroplasty because of painful glenoid erosion.

Crowther, et al (2007), published a case report on a 47 year old female who had syringomyelia, and then developed neuropathic arthropathy. The CT scan showed advanced destruction of the gleno-humeral joint, with some loss of bone stock symmetrically and sclerosis of the glenoid. The patient underwent Copeland resurfacing arthroplasty using an uncemented cobalt-chromium humeral prosthesis along with soft-tissue resurfacing of the glenoid. At 14 months, the patient had mild activity-related pain. X-rays showed the abnormal appearance of apparently progressive sclerosis of the entire glenoid with some new bone formation inferiorly, likely due to uncontrolled pressure of the prosthesis on the glenoid. At 24 months, the patient was satisfied and reported no pain. The authors noted that the glenoid sclerosis needs monitoring with careful assessment of the remaining bone stock using CT scans.

Lee, et al (2009), reported on a retrospective study of patients who underwent cementless Copeland Surface Replacement Arthroplasty of the shoulders with biologic resurfacing of the glenoid using the anterior capsule. The surgery was performed by two surgeons between 1996 and 2005. The indications for the arthroplasty were severe pain and limitation of function in relatively young patients with advanced glenohumeral arthritis but an intact rotator cuff. The average age of the patient was 54.8 years (range 35-68 years). There were 17 patients with 18 operated shoulders available for assessment. The average follow-up was 4.8 years (range 2-10.6 years). The average Constant-Murley score was 71.4 points (range 41-95). The mean sex- and age-adjusted Constant score was 83.9%. The mean American Shoulder and Elbow Surgeons score was 74.4 points (range 35-100). The average arc of forward flexion was 130° (range 100°-160°), abduction was 122° (range 50°-170°), and external rotation by the side was 39° (range 20°-60°). There were 15 of 17 patients (83%) who were satisfied or very satisfied at follow-up and 8 of 17 patients (47%) who could return to their previous sporting activities with minimal or no difficulties. Radiographic follow-up showed that none of the prostheses was loose, but there
was moderate-to-severe glenoid erosion in 9 of 16 shoulders (56%). There were several patients who had adverse outcomes. One patient developed subacromial impingement two years post-op and required arthroscopic subacromial decompression. At 10 years follow-up, x-rays showed severe erosion of the glenoid with superior subluxation of the humeral head. Another patient developed brachial neuritis post-op. Two patients had to have the prosthesis removed. One of these patients had developed a deep infection and required six weeks of parenteral antibiotics. The other patient had a jarring incident, developed pain, and required a revision to a total shoulder arthroplasty. The authors concluded that the procedure is useful in the treatment of younger patients suffering from advanced glenohumeral arthritis of the shoulder. However, the interposed anterior capsule did not protect the glenoid from mid-term erosion by the humeral prosthesis.

Durom Cup Prosthesis

Furest, et al (2007), reported on a prospective study with the Durom cup prosthesis that was conducted in 35 patients (42 shoulders) with pain and limited function associated with rheumatoid arthritis between 1997 and 2000. Thirteen shoulders had a normal rotator cuff or only partial tearing and thinning, another 13 shoulders had a complete rupture with a defect that was repaired. Nine shoulders had a massive rotator cuff tear with a defect of > 5 cm in diameter where the humeral head had migrated under the acromion. These were not repairable, and in these patients the Durom cup was implanted in a slightly more valgus position. The average age of the patients was 61 years (range of 27-78). For 3 patients who died and 3 who did not want to continue in the study, results were only available to the 12-month follow-up. For the remaining 29 patients, assessment at an average 73 months follow-up (all greater than 60 months) showed improvement in the Constant score from 21 to 64. Three shoulders were revised (one due to an oversized cup) and one was converted to total shoulder arthroplasty within the follow-up period. Flexion improved from 64 degrees pre-operatively to 118 degrees at a mean of 73 months after surgery. Radiographs, evaluated by 2 orthopedic surgeons who were blinded to the patients’ identity, showed no change in position and no sign of loosening in 33 of 35 prostheses. Proximal migration (the relationship of the humeral head to the glenoid) increased between 3-month and 73-month follow-up; 22 (63%) of the shoulders had more than a 3-mm increase in proximal migration, and 13 (37%) showed 0 to 2-mm increase in proximal migration over follow-up. Glenoid depth increased significantly in shoulders with either intact or repaired rotator cuffs; 11 (31%) had an increase in depth of 3 mm or more. The authors concluded that humeral resurfacing with the Durom cup had less surgical morbidity and options for salvage if the implant fails, and should be considered as an option along with stemmed or reverse implants in the treatment of the rheumatoid shoulder.

Hemi-CAP Partial Resurfacing

Uribe, et al (2009), reported on one prospective study that described Hemi-CAP partial humeral resurfacing in 11 patients (12 shoulders) who had advanced osteonecrosis measuring less than 40 mm (the size of the largest resurfacing device available). Half of the implants used had a diameter of 35 mm and the remaining half had a diameter of 30 mm. None of the patients had rotator cuff or labral pathology, and no patient required glenoid resurfacing. Assessments performed at 3, 6, 12, 18, 24, 36, and 48 months after implantation included the Western Ontario Osteoarthritis of the Shoulder (WOOS) index, the Shoulder Score Index from the American Shoulder and Elbow Surgeons (ASES) evaluation form, the Constant score, and a visual analog
score (VAS) for pain. No patient was lost to follow-up. Significant improvement in function was observed at an average 30 months (range, 21-57) follow-up; the WOOS improved from 1,421 to 47, the mean Shoulder Score Index improved from 24 to 75 (max of 100) and the mean Constant score improved from 23 to 62 (max of 100). Active forward elevation improved from a mean of 94 degrees to 142 degrees. All patients reported pain relief, and VAS pain scores improved from 75 at baseline to 16 at follow-up. There was no evidence of implant loosening. The authors concluded that results are promising at 30 months, but longer follow-up is required to evaluate the survivorship of the implant and its effect on the glenoid.

Burgess DL, et al (2009), published a review of shoulder resurfacing. They noted that humeral resurfacing has been associated with low complication rates. There has been one intraoperative periprosthetic fracture reported. The most frequently reported complications include loosening of the prosthesis and glenoidal erosion. In patients with rheumatoid arthritis, common sequelae include glenoidal erosion and proximal migration of the cup. The authors noted that additional studies are needed to further assess the complication of prosthetic loosening and the long-term follow-up. Future studies are necessary to evaluate alternative surface bearing materials and to determine the long-term success rate.

Summary
Shoulder resurfacing has the potential to improve pain and function to the same extent as total shoulder replacement or hemiarthroplasty, while at the same time reducing risks from the surgical procedure, preserving bone stock and reducing the difficulty with revision procedures. At this time, however, evidence in support of these proposed benefits is limited/lacking. For some implant designs, the published literature consists of one small case series. The 4 independent case series identified on the Copeland prosthesis suggest better short-term outcomes with total shoulder resurfacing or total shoulder arthroplasty than humeral head resurfacing alone. This is similar to findings of recent systematic reviews that compared hemiarthroplasty with total shoulder arthroplasty; the choice of these two procedures remains controversial due to the differing effects on glenoid erosion and glenoid component loosening. For shoulder resurfacing, questions remain about the stability and durability of these prostheses, as well as the effect of partial or total humeral resurfacing on the glenoid. Controlled studies are needed to evaluate the risks and benefits of hemi- and total shoulder resurfacing in comparison with hemi- and total shoulder replacement. Several clinical trials are in progress, with estimated completion dates of 2013. At the present time, evidence is insufficient to permit conclusions concerning the effect of this procedure on health outcomes. Therefore, partial resurfacing, humeral resurfacing and total shoulder resurfacing are considered investigational.

November 2010 update
A search for new peer-reviewed published literature did not identify new articles. Two clinical trials are ongoing and one trial was terminated early due to limited enrollment and follow-up. The other clinical trial has been completed (last update August, 19, 2010) with no study results published at this time.

The policy coverage statement remains unchanged at this time.
**Key Words:**
Resurfacing, shoulder, total shoulder, Mark-3, Mark-1, Mark-2, Copeland Extended Articulating Surface (EAS) Resurfacing Heads, DuPuy Global Cap, Axiom Shoulder Resurfacing System

**Approved by Governing Bodies:**
Copeland™ Extended Articulating Surface (EAS)™ Resurfacing Heads (Biomet Manufacturing)—FDA 510(k) approval July 7, 2005
DePuy Global CAP™ CTA Resurfacing Shoulder Humeral Head (DePuy)—FDA 510(k) approval June 8, 2008
Axiom Shoulder Resurfacing System (Axiom Orthopaedics)—FDA 510(k) approval July 6, 2006
HemiCAP® (Arthrosurface) (Contoured Articular Prosthetic (CAP) Humeral Head Resurfacing Prosthesis)—FDA 510(k) approval January 10, 2003

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

ITS: Home Policy provisions apply
FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity. Pre-certification requirements: Not applicable

**CURRENT Coding:**
CPT Codes: There are no CPT codes specific to resurfacing of the shoulder. In the absence of a specific code, the preferable code to use would be the CPT code for unlisted procedure of the shoulder (23929).

Codes 23470 and 23472 should not be used to report this procedure.

**References:**

Policy History:
Medical Policy Group, July 2009 (3)
Medical Policy Administration Committee, August 2009
Available for comment August 10-September 23, 2009
Medical Policy Group, November 2009 (3)
Medical Policy Group, November 2010 (1) No changes to policy, Statement added to Key Points
Medical Policy Group, March 2012: Effective March 12, 2012 Active policy but no longer scheduled for regular literature reviews and update.

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.