Policy Number	**SUR705.032**
Policy Effective Date	**11/15/2024**

Shoulder Resurfacing

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Shoulder resurfacing, including total, hemi, or partial resurfacing, **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

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) or in combination with glenoid resurfacing (total shoulder resurfacing, TSR). With TSR, the glenoid may be 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 current 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.

Regulatory Status

Several prosthetic designs are currently available in the United States (U.S.). Developed by Copeland and colleagues, the Mark prosthesis is currently in its third generation in Europe. The Copeland™ Mark-1 had a central pegged humeral component that 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 U.S. 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; and traumatic arthritis.

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).

In 2006, the Aequalis Resurfacing Head (Tornier) was cleared for marketing by the FDA. Joint replacement with this device is indicated to relieve severe pain or significant disability due to humeral head fracture or for degenerative pathologies such as osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, and necrosis of the humeral head. (1)

Rationale

No randomized trials on shoulder resurfacing were identified. For the Copeland™ prosthesis, 5 case series and 1 matched-pair analysis were identified. Three of the 6 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. Additional case series using 3 different prosthetic designs were also identified. Resurfacing has been reported in patients with osteoarthritis, rheumatoid arthritis, osteonecrosis of the humeral head, instability arthropathy, post-traumatic arthropathy, and postsurgical glenohumeral arthritis. The largest prospective and/or consecutive series are described below. In addition, a search of peer reviewed literature through December 2014 also identified no new clinical trial publications or any additional information that would change the coverage position of this medical policy. No random control studies were identified with this update, studies identified were smaller studies. (2, 3)

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.

Bryant et al. conducted a meta-analysis of 4 randomized trials that compared total shoulder arthroplasty with humeral head replacement or hemiarthroplasty. (4) 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 University of California at Los Angeles (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 versus 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. 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. (5) 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 (1,185 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.

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. (6) Out of the series, 1 patient died less than 24 months after shoulder replacement and 4 patients were lost to follow-up, resulting in a 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, 22 to 88 years). 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 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. (7, 8) Overlap in patients between these publications is likely.

Another group from England reported outcomes from a consecutive series of 52 patients (56 shoulders) who received humeral resurfacing with the Copeland™ Mark-3 prosthesis. (9) 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 up for more than 4 years. The primary diagnosis was osteoarthritis in 20 patients, rheumatoid arthritis in 26, post-traumatic arthrosis in 1 and rotator cuff arthropathy in 1. The average age was 70 years (range 34–84). Independent postoperative 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 1 patient had a fracture, resulting in an estimated 98% implant survival at 4 years (92% survival for any revision). 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. (10) 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.

A prospective study with the Durom cup prosthesis was conducted in 35 patients (42 shoulders) with pain and limited function associated with rheumatoid arthritis between 1997 and 2000. (11) Thirteen shoulders had a normal rotator cuff or only partial tearing and thinning, and 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 follow-up of 73 months (all greater than 60 months) showed improvement in the Constant score from 21 to 64. Three shoulders were revised (1 due to an oversized cup) and 1 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 two 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 the 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.

A 2007 review article briefly described short-term outcomes (3-24 months) of 62 patients from 6 institutions who underwent humeral resurfacing with the HemiCAP. (12) In 2009, HemiCAP® partial humeral resurfacing was reported in a prospective study of 11 patients (12 shoulders) who had advanced osteonecrosis measuring less than 40 mm (the size of the largest resurfacing device available). (13) One half of the implants used had a diameter of 35 mm and the other 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 analogue score (VAS) for pain. No patient was lost to follow-up. Significant improvement in function was observed at an average follow-up of 30 months (range, 21–57 months); the WOOS improved from 1421 to 471 (worst score, 1900); the mean Shoulder Score Index improved from 24 to 75 (maximum of 100); and the mean Constant score improved from 23 to 62 (maximum 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.

In 2017, Geervliet et al. reported the mid-term results of the Global C.A.P. uncemented resurfacing shoulder prosthesis (DePuy Synthes). From January 2007 to December 2009, 48 humeral cementless resurfacing prostheses in 46 patients (12 males, 34 females) (mean age of 72 years, range 59-89) were performed. All patients were diagnosed with primary glenohumeral osteoarthritis. Patients were contacted for review; the Constant score, visual analog pain scale, Dutch Simple Shoulder Test, SF-12 scores and physical examination were assessed both preoperatively and yearly postoperatively. Complications and revision surgery were documented. Radiographs were evaluated for component size, offset, inclination, height, loosening and subluxation. At a mean 6.4-year follow-up (range 5-8), the Constant score, visual analog pain scale and the Dutch Simple Shoulder Test scores improved significantly ($p < 0.05$) from baseline. Three patients were lost to follow-up. One patient died, and two patients were not able to attend the follow-up appointments, due to other health-related issues. Eleven patients (23%) had a revision operation. The most important findings of this study of the Global C.A.P. shoulder resurfacing arthroplasty were an increase of range of motion, a reduction of pain complaints, but a concerning high rate of revision after mid-term follow-up. (14)

Soudy et al. (2017) assessed the clinical and computed tomography (CT) outcomes at least 2 years after humeral head resurfacing to treat concentric glenohumeral osteoarthritis in a single center retrospective study. The study included patients with Copeland™ (n=40) and Aequalis™ (n=65) humeral resurfacing heads implanted between 2004 and 2012. Mean patient age at diagnosis was 64 years. The diagnoses were osteoarthritis with an intact (68%) or torn (21%) rotator cuff, avascular necrosis (5%), osteoarthritis complicating chronic instability (3%), post-

traumatic osteoarthritis (2%), and chronic inflammatory joint disease (1%). Validated clinical scores, radiographs, and CT before surgery and at last follow-up were compared. During the mean follow-up of 56 months, complications occurred in 24 implants. Revision surgery with reverse shoulder replacement was required in 18 cases, after a mean of 43.6 months, to treat glenoid wear or a rotator cuff tear. At last follow-up, for the implants that did not require revision surgery, the mean Constant score was 64/100. The implants had a mean varus of 5° and mean retroversion of -13.3°. The mean increase in glenoid cavity depth was 2.4mm. Mean increases in medial and lateral humeral offset were 1.9mm and 2.7mm, respectively. Pre-operative factors significantly associated with failure were rotator cuff tear (P=0.017) and glenoid erosion (P=0.001). Investigators found a high failure rate related to glenoid wear or progressive rotator-cuff impairment, although CT showed no evidence of implant malposition or overstuffing. Previous studies of stemmed humeral head implants showed better outcomes. The authors concluded that given the low medium-term prosthesis survival rate, they now reserve humeral head resurfacing for concentric osteoarthritis without glenoid erosions or rotator cuff damage. (15)

Summary of Evidence

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 small case series. In 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. 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 experimental, investigational and/or unproven.

Practice Guidelines and Position Statements

American Academy of Orthopedic Surgeons (AAOS)

In 2020 (last updated July 29, 2022), the American Academy of Orthopedic Surgeons published evidence-based clinical practice guidelines for the management of glenohumeral joint osteoarthritis. (16) The practice guidelines state that the strength of recommendation for support that clinicians may utilize stemmed, stemless, or resurfacing prosthesis for patients with glenohumeral joint osteoarthritis undergoing total or hemiarthroplasty is “Limited.” See Table 1 for descriptions of the strength of recommendations. The rationale for this recommendation includes 4 low quality studies.

Table 1. Strength of Recommendation Descriptions

Strength	Overall Strength of Evidence	Description of Evidence Quality	Strength Visual
Strong	Strong	Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.	★★★★
Moderate	Moderate	Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.	★★★
Limited	Low or conflicting Evidence	Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	★★
Consensus	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the systematic literature review development group is making a recommendation based on their clinical opinion.	★

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	23470, 23472, 23929
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	Document updated with literature review. Coverage unchanged. No new references added.
07/15/2023	Reviewed. No changes.
01/01/2023	Document updated with literature review. Coverage unchanged. Reference 16 added; some updated and others removed.
04/01/2021	Reviewed. No changes.
05/01/2020	Document updated with literature review. Coverage unchanged. Reference 16 added.
11/15/2018	Reviewed. No changes.
01/15/2018	Document updated with literature review. Coverage unchanged.
07/01/2016	Reviewed. No changes.
02/01/2015	Document updated with literature review. Coverage unchanged.
09/15/2013	Document updated with literature review. Coverage unchanged.
05/15/2011	Document updated with literature review. Coverage unchanged.
11/15/2009	New policy with literature search through June 2009, coverage experimental, investigational and unproven.