

Medical Policy Reference Manual Medical Policy

7.01.115 Shoulder Resurfacing Arthroplasty

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Description

Resurfacing of the shoulder joint at the humeral head with or without resurfacing of the glenoid is a surgical treatment for degenerative joint disease / arthritis of the shoulder joint. The technique involves attachment of a hemispherical shaped metallic ball that partially replaces the diseased humeral head with minimal resection of bone. Thus, the intent of resurfacing is to preserve the patient's bone stock and natural bony anatomy as much as possible, unlike the more traditional prosthetic joint apparatus, which has a long stem that protrudes deep into the shaft of the humerus. Proponents of resurfacing have proposed that the technique provides a more natural motion and stability, particularly for younger, more active patients, as well as shortened operative time, reduced blood loss, and easier re-operations if necessary.

Policy

Shoulder resurfacing arthroplasty is considered **experimental / investigational** as it does not meet TEC criteria #2-5.

Policy Guidelines

Experimental/Investigational

The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted by the BlueCross BlueShield Association (BCBSA) Medical Policy Services (MPS) Assessment Criteria (formerly known as the TEC Criteria or "Technology Evaluation Center" criteria are deemed to be experimental/investigational:

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

* Technology includes drugs, devices, processes, systems, or techniques

Rationale:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

The prosthetic devices for shoulder resurfacing are regulated under the 510(k) process as Class II devices. Several such devices have been cleared for U.S. distribution, most notably the Copeland™ Resurfacing Head (Biomet, Inc.) beginning in December of 2000. Clearances for updated designs have been issued as late as 2008.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

Even though shoulder resurfacing prostheses have been available for over ten years, there have been only a few, small, uncontrolled studies assessing safety and efficacy. Levy and Copeland's consecutive series published in 2001 reported on 103 operations on 94 patients. The subjects had a variety of conditions, including osteoarthritis, rheumatoid arthritis, avascular necrosis, post-traumatic arthropathy and instability arthropathy. The Constant shoulder score was the primary outcome measure, and significant improvements were observed from baseline at an average 6.8 years

postoperatively in the 98 shoulders available for follow-up. A 2005 series by Thomas et al (n=56) also reported significant Constant score increases over 4 years follow-up with 98% implant survival. Another series from a group led by the same author also reported Constant score improvement over a short term (3-year) follow-up period. There is a possible overlap of patients in these studies. Another uncontrolled study by Baille and colleagues (2008) studied 36 relatively young patients over a 2-year period and reported significant improvements in American Shoulder and Elbow Surgeons score and Single Assessment Numeric Evaluation score. 35 patients indicated they were satisfied with the procedure. A German series by Buchner et al (2008) reported on a matched-pair analysis comparing the results of 22 patients who underwent resurfacing with the Copeland prosthesis to 22 patients who underwent total shoulder arthroplasty. The authors reported that at 12-month follow-up, patient with total shoulder arthroplasty demonstrated greater Constant score improvement than those who received humeral resurfacing. All these studies involved the Copeland prosthesis.

In 2021, a systematic review was completed by 2 independent reviewers (Meaie, J. J., Patterson, D. C., Anthony, S. G., Parsons, B. O., & Cagle, P. J.). Eleven studies of 268 shoulders in 264 patients reported significantly improved American Shoulder and Elbow Surgeons Visual Analog Scale, and Simple Shoulder Test scores postoperatively. 43.3% were failures and infections were found in 12/235. A 2021 systematic review of surgical treatment of humeral head avascular necrosis in patients with sickle cell disease (Alkhateeb, J. M., Arafah, M. A., Tashkandi, M., & Al Qahtani, S. M) reviewed humeral head resurfacing as an alternative or revision of core decompression with initial significant improvement in functional scores. However, revision was required for the presence of osteonecrosis at the resurfacing stem, glenoid wear, and scapular insufficiency. A 2022 systematic review (Fonte, H., Amorim-Barbosa, T., Diniz, S., Barros, L., Ramos, J., & Claro, R.) revealed unacceptable revision rates (34.5%) in Hemiarthroplasty with biological resurfacing (HABR) patients.

Overall, there is insufficient evidence to permit conclusions regarding health outcomes. The available studies are small and uncontrolled, with short follow-up periods and mixed patient populations. The evidence indicates the technique is worthy of further investigation, but controlled studies are needed to address patient selection and the results in context of the different conditions for which it can be used.

3. The technology must improve the net health outcome:

In the short term, based on the limited available evidence the procedure is safe. Follow-up periods, however, are too short to reach conclusions regarding the durability of any improvements in performance scores and the stability of the joint structures. Therefore, it is unknown whether the procedure improves net health outcomes.

4. The technology must be as effective as any established alternatives:

Controlled studies are needed to assess whether resurfacing is at least as effective as total- or hemiarthroplasty. The Buchner study, though limited, suggests that resurfacing may not be at least as effective as the total- or hemiarthroplasty in terms of Constant score improvement. The American Academy of Orthopedic Surgeons, in a 2009 evidence-based guideline concluded that hemiarthroplasty and total shoulder arthroplasty are acceptable options for treatment of glenohumeral joint arthritis. The guideline also states there is insufficient evidence to support the use of humeral resurfacing.

5. The improvement must be attainable outside the investigational settings:

The evidence has not established that there is a net improvement in the investigational settings. Therefore, it is not possible to know if an improvement outside of investigational settings can be expected.

Update 2022:

A search of the peer-reviewed literature was performed from the period of December 2019 through October 2022. Findings in the recent literature do not change the conclusions regarding shoulder resurfacing arthroplasty. Therefore, the policy statement remains experimental / investigational.

Update 2020:

A search of the peer-reviewed literature was performed from the period of December 2017 through December 2019. Findings in the recent literature do not change the conclusions regarding shoulder resurfacing arthroplasty. Therefore, the policy statement remains experimental / investigational.

Update 2017:

A search of the peer-reviewed literature was performed from October 2015 through November 2017. Findings in the current literature do not change the conclusions that shoulder resurfacing arthroplasty is considered experimental/investigational. Therefore, the policy statement is unchanged.

Update 2015:

A search of the peer-reviewed literature was performed from August 2013 through September 2015. Findings in the current literature do not change the conclusions that shoulder resurfacing arthroplasty is considered experimental/investigational. Therefore, the policy statement is unchanged.

Update 2013:

A search of the peer-reviewed literature was performed from September 2011 through July 2013. Findings in the current literature do not change the conclusions that shoulder resurfacing arthroplasty is considered experimental/investigational. Therefore, the policy statement is unchanged.

Benefit Applications

There are no Benefit Application guidelines for this Medical Policy

Provider Guidelines

Report the procedure for shoulder resurfacing arthroplasty with the CPT® Category I unlisted procedure code, shoulder.

Cross References to Related Policies and Procedures

There are no Related Policies for this Medical Policy

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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This policy statement relates only to the services or supplies described herein. Coverage will vary from contract to contract and by line of business and should be verified before applying the terms of the policy.