

Corporate Medical Policy

Reverse Shoulder Arthroplasty

File Name: reverse_shoulder_arthroplasty
Origination: 10/2009
Last CAP Review: 7/2010
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Active policy, no longer scheduled for routine literature review

Description of Procedure or Service

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

The reverse shoulder prosthesis (RSP) was specifically designed to address the limitations of conventional prostheses in patients with a non-functioning irreparable rotator cuff. Biomechanically, the RSP moves the center of rotation of the arm laterally and changes the direction of the pull of the deltoid muscle, allowing the deltoid to elevate the arm without functioning rotator cuff tendons. It is proposed that the RSP may provide a viable surgical solution for salvaging function in patients with irreparable non-functioning rotator cuffs. The primary indication is painful and symptomatic rotator-cuff tear arthropathy, characterized by superior subluxation of the humeral head in conjunction with glenohumeral arthrosis. Also being investigated are failed shoulder arthroplasty (total shoulder or hemiarthroplasty) where a non-functioning rotator cuff results in superior subluxation of the conventional prosthesis; rheumatoid arthritis where there is associated rotator-cuff arthropathy; and post-traumatic arthritis with rotator-cuff dysfunction. Implantation of the RSP is considered to be a technically challenging surgical procedure that may be associated with a high complication rate. Device-specific complications include notching of the inferior scapula, baseplate fixation failures, and dislocation of the prosthesis.

The first RSP (Delta) was developed in France in 1985; it is frequently described by the name of its designer as the Grammont reverse shoulder prosthesis. The redesigned Delta III prosthesis, marketed by DePuy, has been used in Europe since 1991. DePuy received marketing clearance for the Delta III Reverse Shoulder prosthesis in the United States through the U.S. Food and Drug Administration (FDA) 510(k) process in 2003 and for the Delta Xtend™ Reverse Shoulder System in 2007. The Tournier Aequalis Reverse Shoulder prosthesis received 510(k) clearance for marketing in 2004. The Trabecular Metal™ Reverse Shoulder System (Zimmer) and the Encore® Reverse® Shoulder Prosthesis (Encore Medical) received 510(k) marketing clearance in 2005. The

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SMR Modular Shoulder System (Systema Multiplana Randelli, Italy) is not presently cleared for marketing in the United States.

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."

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for reverse shoulder arthroplasty when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Reverse Shoulder Arthroplasty is covered

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

- Failed hemiarthroplasty or failed total shoulder arthroplasty with irreparable rotator cuff deficiency;
- Comminuted fractures (3 or 4 part) of the proximal humerus in an older population (e.g., 65 years of age or older);
- Non-functioning irreparable rotator cuff and glenohumeral arthropathy.

When Reverse Shoulder Arthroplasty is not covered

Reverse shoulder arthroplasty is considered investigational for all other conditions.

Policy Guidelines

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-

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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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: There is no specific code for reverse shoulder arthroplasty. The procedure is most likely coded using a shoulder arthroplasty code (CPT 23472) or an unlisted shoulder procedure code (CPT 23929).

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Boileau P, Watkinson D, Hatzidakis AM et al. Neer Award 2005: the Grammont reverse shoulder prosthesis: results in cuff tear arthritis, fracture sequelae, and revision arthroplasty. *J Shoulder Elbow Surg* 2006; 15(5):527-40.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.114, 8/13/09

Specialty Matched Consultant Advisory Panel review 7/2010

Policy Implementation/Update Information

11/9/09 New policy issued. Reverse shoulder arthroplasty may be considered medically necessary in patients with the following conditions when no alternative treatment would be expected to provide an acceptable clinical outcome: failed hemiarthroplasty or failed total shoulder arthroplasty with irreparable rotator cuff deficiency; comminuted fractures (3 or 4 part) of the proximal humerus in an older population (e.g., 65 years of age or older); non-functioning irreparable rotator cuff and glenohumeral arthropathy. (adn)

8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. Medical Policy number removed. (mco)

2/1/2011 Policy status changed to “Active archive, no longer scheduled for routine literature

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review.” (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.