Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Shoulder Resurfacing

Policy #: 366
Latest Review Date: June 2023
Category: Surgery
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **shoulder resurfacing**, including total, hemi, or partial resurfacing, as a **non-covered benefit** and as **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.

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).

KEY POINTS:

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 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.

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.

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.

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POLICY HISTORY:

Adopted for Blue Advantage, July 2009
Available for comment July 20-September 2, 2009
Medical Policy Group, November 2010: 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.
Medical Policy Group, June 2021: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, July 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, June 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.