MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**SHOULDER ARTHROPLASTY (TOTAL, PARTIAL AND REVERSE)**
Policy Number	**7.01.95**
Category	**Technology Assessment**
Effective Date	**6/21/18**
Revised Date	**12/20/18, 12/19/19**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based on our criteria and assessment of the peer-reviewed literature, *total shoulder arthroplasty* has proven to be medically effective and is therefore considered **medically appropriate** when **ALL** of the following criteria have been met:
   A. Function-limiting pain (e.g., loss of shoulder function which interferes with the ability to carry out age appropriate activities of daily living and/or demands of employment) for at least three (3) months in duration;
   B. Failure of at least three (3) months of provider-directed non-surgical management
   C. Radiographic imaging and/or an advanced diagnostic procedure (i.e., MRI, CT scan), is conclusive for the presence of advanced destructive degenerative joint disease (i.e., osteoarthritis, rheumatoid arthritis, avascular necrosis) that correlates with the individual's reported symptoms and physical exam findings including marked narrowing of the joint space and ONE or MORE of the following:
      1. Irregular joint surfaces;
      2. Glenoid sclerosis;
      3. Glenoid osteophyte changes;
      4. Flattened glenoid; or
      5. Cystic changes in the humeral head.

II. Based on our criteria and assessment of the peer-reviewed literature, *hemi-arthroplasty (replacement)* of the shoulder has proven to be medically effective and is therefore considered **medically appropriate** when **ALL** of the following criteria have been met:
   A. Function-limiting pain (e.g., loss of shoulder function which interferes with the ability to carry out age appropriate activities of daily living and/or demands of employment) for at least three (3) months in duration;
   B. Failure of at least three (3) months of provider-directed non-surgical management; and
   C. Radiographic imaging and/or an advanced diagnostic procedure (i.e., MRI, CT scan), is conclusive for the presence of ANY of the following and correlates with the individual's reported symptoms and physical exam findings:
      1. Advanced destructive degenerative joint disease (i.e., rheumatoid arthritis or osteoarthritis) resulting in marked narrowing of the joint space;
      2. Arthritic conditions in which the glenoid bone stock is inadequate to support a glenoid prosthesis;
      3. Rotator cuff tear arthropathy (i.e., severe rotator cuff tearing and end-stage arthritic disease);
      4. Avascular necrosis without glenoid involvement.

III. Based on our criteria and assessment of peer-reviewed literature, *hemi-arthroplasty (replacement)* has been medically proven to be effective and is considered **medically appropriate** when radiographic imaging and/or an advance diagnostic study (i.e., MRI, CT scan) is conclusive for the presence of a proximal humerus fracture that is not amenable to internal fixation. Criteria for duration and severity of symptoms, physical examination findings, and provider-directed non-surgical management are not required to be met.

IV. Based on our criteria and assessment of peer-reviewed literature, *hemi-arthroplasty (replacement)* and *total shoulder arthroplasty* have not been medically proven to be effective and are considered **not medically necessary** for any other indication or condition, even if one or more of the following criteria are present:
   A. Active local or systemic infection;
   B. Paralytic disorder of the shoulder (e.g., flail shoulder due to irreversible brachial plexus palsy, spinal cord injury, or neuromuscular disease);
   C. One or more uncontrolled or unstable medical conditions that would significantly increase the risk or morbidity (e.g., cardiac, pulmonary, liver, genitourinary, or metabolic disease, hypertension, abnormal serum electrolyte levels); or
   D. Charcot joint.

V. Based on our criteria and assessment of peer-reviewed literature, *reverse total shoulder arthroplasty (replacement)* has been medically proven to be effective and is considered **medically appropriate** when **ALL** the following criteria have been met:
   A. Function-limiting pain (e.g., loss of shoulder function which interferes with the ability to carry out age appropriate activities of daily living and/or demands of employment) for at least three (3) months in duration;
   B. The individual must possess functional use of the deltoid muscle;
   C. At least 90 degrees of passive shoulder range of motion (elevation/flexion);
   D. Failure of at least three (3) months of provider-directed non-surgical management; and
   E. Presence of ANY of the following:
      1. Deficient rotator cuff with severe glenohumeral arthropathy and limited ability to actively flex the upper extremity to 90 degrees against gravity (i.e., rotator cuff tear arthropathy);
      2. Pseudoparalysis from an irreparable rotator cuff tear (i.e., active forward flexion less than 90 degrees with full passive motion);
      3. Failed hemi-arthroplasty or total shoulder replacement with a deficient rotator cuff that is non-repairable; or
      4. Required reconstruction after a tumor resection.

VI. Based on our criteria and assessment of peer-reviewed literature, *reverse total shoulder arthroplasty (replacement)* has been medically proven to be effective and is considered **medically appropriate** when radiographic imaging and/or an advanced diagnostic study (i.e., MRI, CT scan) is conclusive for the presence of a shoulder fracture that is not repairable or cannot be reconstructed with other techniques. Criteria for duration and severity of symptoms, physical examination findings, and provider-directed non-surgical management are not required to be met.

VII. Based on our criteria and assessment of peer-reviewed literature, *reverse total shoulder arthroplasty (replacement)* has not been medically proven to be effective and is considered **not medically necessary** for any other indication or condition, even if one or more of the following criteria are present:
   A. Active local or systemic infection;
   B. Paralytic disorder of the shoulder (e.g., flail shoulder due to irreversible brachial plexus palsy, spinal cord injury, or neuromuscular disease);
   C. Deltoid deficiency (e.g., axillary nerve palsy);
   D. One or more uncontrolled or unstable medical conditions that would significantly increase the risk or morbidity (e.g., cardiac, pulmonary, liver, genitourinary, or metabolic disease, hypertension, abnormal serum electrolyte levels); or
   E. Charcot joint.

VIII. Based on our criteria and assessment of peer-reviewed literature, *revision of shoulder arthroplasty (replacement)* has been medically proven to be effective and is considered **medically appropriate** for an individual who has previously undergone a hemi or total shoulder arthroplasty and one or more of the following criteria have been met:
   A. Presence of ANY of the following:
      1. Recurrent prosthetic dislocation not responsive to a reasonable course of non-surgical care;
      2. Instability of the components;
      3. Aseptic loosening;
      4. Periprosthetic infection; or
      5. Periprosthetic fracture.

B. Unexplained function-limiting pain (e.g., loss of shoulder function which interferes with the ability to carry out age-appropriate activities of daily living and/or demands of employment) for greater than six (6) months and which is unresponsive to provider-directed non-surgical management.

IX. Based on our criteria and assessment of peer-reviewed literature, *revision of shoulder arthroplasty (replacement)* has not been medically proven to be effective and is considered **not medically necessary** for the treatment of any other indication or condition, including Charcot joint.

DESCRIPTION

Total shoulder replacement, also known as total shoulder arthroplasty (TSA), is a surgical procedure for treating the severe pain and stiffness that often result at the end stage of various forms of arthritis or degenerative joint disease of the shoulder joint. The primary goal of shoulder replacement surgery is pain relief, with a secondary benefit of restoring motion, strength, function, and assisting with returning patients to an activity level as near to normal as possible. Painful shoulder arthritis refers to the disappearing of the normally smooth cartilage surfaces of the shoulder, which permit the ball and socket to smoothly glide against one another. This disappearance of cartilage covering results in a "bone on bone" joint and can be quite painful. Thus new surfaces provide the answer for restoration of comfort. The actual surgery involves replacing the damaged humeral head (or joint "ball") with a metal ball, and putting a new smooth plastic surface on the glenoid (called the "socket"). Metal on plastic surfaces (rather than metal on metal) are the hallmark of virtually all shoulder replacement implant systems.

Shoulder hemiarthroplasty, also called partial shoulder replacement, is a surgical procedure during which the upper bone in the arm (humerus) is replaced with a prosthetic metal implant, and the other half of the shoulder joint (glenoid or socket) is left intact. Hemi arthroplasty is a highly technical procedure. There are two types of hemiarthroplasties– stemmed hemi arthroplasty and resurfacing hemi arthroplasty. The surgeon will determine the type of procedure based on the nature of the injury and the condition of the shoulder.

Reverse shoulder arthroplasty involves replacing both the humeral head and the glenoid, but the ball and socket are reversed to improve muscle function. This allows the deltoid muscle, which has a longer movement arm, to generate greater force, allowing it to act in place of an inadequate functioning or torn rotator cuff.

RATIONALE

In a systematic review and meta-analysis, Carter and colleagues characterized the change in generic and shoulder-specific health-related quality-of-life (QOL) measures resulting from TSA. These investigators identified published studies reporting pre-operative and post-operative health-related QOL outcomes for patients receiving TSA. Health-related QOL measures were identified, and meta-analysis was used to calculate standardized mean differences (SMDs, reflective of the effect size) and 95 % CI for each scale. A total of 20 studies (1,576 TSA) met the inclusion criteria. Outcome measures were analyzed after an average post-operative follow-up duration of 3.7 +/- 2.2 years. The Short Form-36 demonstrated significant improvement in physical component summary scores (SMD = 0.7, $p < 0.001$) but not in mental component summary scores (SMD = 0.2, $p = 0.37$). Significant improvements were observed in the visual analog scale score for pain (SMD = -2.5, $p < 0.001$) and scores on 3 shoulder-specific measures: the Constant score (SMD = 2.7, $p < 0.001$), American Shoulder and Elbow Surgeons score (SMD = 2.9, $p < 0.001$), and Simple Shoulder Test (SMD = 2.3, $p < 0.001$). The authors concluded that TSA leads to significant improvements in scores for function and pain. Shoulder-specific measures of function consistently showed the greatest degree of improvement, with large effect sizes. They noted that TSA also leads to significant improvements in overall physical well-being, with a moderate-to-large effect size.

In a multi-center, retrospective study, Favard and colleagues evaluated the rate of complications and the functional improvement with different types of shoulder arthroplasties after a minimum follow-up of 8 years. A total of 198 shoulders including 85 primary OA of the shoulder, 76 rotator-cuff tear arthropathies, 19 avascular necrosis, and 18 RA were included in this study. Arthroplasties included 104 anatomic TSA, 77 reverse arthroplasties and 17 hemiarthroplasties. Ten patients had their arthroplasty revised, and 134 patients with TSA were able to be present at the final follow-up or provide information on their case. Function was evaluated by the Constant-Murley score and loosening by standard radiographs. In the group with primary OA of the shoulder, there were 8 complications (11 %) including 6 (8.3 %) requiring implant revision. In the group of rotator-cuff arthropathies, there were 9 (14.7 %) complications

including 4 (6.5 %) requiring implant revision. In the group with RA, there was one complication, and no surgical revision was necessary. There were no complications in the group with avascular necrosis. Glenoid migration occurred in 28.5 % of anatomic TSA, and 3.4 % of reverse arthroplasties. This difference was significant ($p < 0.001$). The Constant-Murley score was significantly improved in all etiologies. The authors concluded that glenohumeral arthropathies can be successfully treated by arthroplasty. Anatomic TSA was shown to be associated with a high-risk of glenoid loosening at radiographic follow-up, which made them hesitate to use the cemented polyethylene implant, especially in young patients.

In a Cochrane review, Singh et al. determined the benefits and harm of surgery for shoulder OA. These investigators performed a systematic review of clinical trials of adults with shoulder OA, comparing surgical techniques (TSA, hemiarthroplasty, implant type and fixation) to placebo, sham surgery, non-surgical modalities, and no treatment. They also reviewed trials that compared various surgical techniques, reporting patient-reported outcomes (pain, function, quality of life, etc.) or revision rates. They calculated the risk ratio for categorical outcomes and mean differences for continuous outcomes with 95 % confidence interval (CI). There were no controlled trials of surgery versus placebo or non-surgical interventions. A total of 7 studies with 238 patients were included. Two studies compared TSA to hemiarthroplasty (n = 88). Significantly worse scores on the 0 to 100 American Shoulder and Elbow Surgeons scale (mean difference, -10.05 at 24 to 34 months; 95 % CI: -18.97 to -1.13; p = 0.03) and a non-significant trend toward higher revision rate in hemiarthroplasty compared to TSA (relative risk 6.18; 95 % CI: 0.77 to 49.52; p = 0.09) were noted. With 1 study providing data (n = 41), no differences were noted between groups for pain scores (mean difference 7.8; 95 % CI: -5.33 to 20.93), quality of life on Medical Outcomes Study Short-Form 36 physical component summary (mean difference 0.80; 95 % CI: -6.63 to -8.23), and adverse events (relative risk 1.2; 95 % CI: 0.4 to 3.8). The authors concluded that TSA was associated with better shoulder function, with no other demonstrable clinical benefits compared to hemiarthroplasty. They stated that more studies are needed to compare clinical outcomes between them and comparing shoulder surgery to sham, placebo, and other non-surgical treatment options.

The available evidence from retrospective uncontrolled trials indicates that use of the reverse shoulder arthroplasty 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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement [e.g. total shoulder])
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component

HCPCS Codes

Code	Description
None	

ICD10 Codes

Code	Description
M05.00 - M05.9	Rheumatoid arthritis (code range)
M12.511 - M12.519	Traumatic arthropathy, shoulder (code range)
M19.011 - M19.019	Osteoarthrosis, localized, primary, shoulder region (code range)
M19.111 - M19.119	Post-traumatic osteoarthritis, shoulder (code range)
M19.211 - M19.219	Osteoarthrosis, localized, secondary, shoulder region (code range)
M24.811 - M24.819	Other specific joint derangement of shoulder, not elsewhere classified [crepitus] (code range)
M87.021 - M87.029	Idiopathic aseptic necrosis of humerus [head] (code range)
S42.001K - S42.199P	Malunion or nonunion of fracture of shoulder (code range)
S42.201A - S42.496S	Fracture of humerus (code range)
T84.018A - T84.019A	Broken internal joint prosthesis [shoulder] (code range)
T84.028A- T84.029A	Dislocation of other and unspecified internal joint prosthesis (code range)
T84.038A - T84.039A	Mechanical loosening of other or unspecified prosthetic joint [shoulder] (code range)
T84.59XA	Infection and inflammatory reaction due to other internal joint prosthesis [shoulder]

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*Key Article

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, shoulder arthroplasty is not addressed in specific National or Regional Medicare coverage determinations or policies