Oscar Clinical Guideline: Total Shoulder Arthroplasty (Replacement) and Reverse Total Shoulder Arthroplasty (CG076, Ver. 4)

Total Shoulder Arthroplasty (Replacement) and Reverse Total Shoulder Arthroplasty

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The entire shoulder is made of the humerus (upper arm bone), scapula (shoulder blade), and the clavicle (collarbone). The muscles and tendons around the shoulder provide support and stability. Total shoulder arthroplasty (TSA) or total shoulder replacement is a surgical reconstruction or replacement of the humeral head (ball) and the glenoid (socket) to make the glenohumeral joint. There are two types of total shoulder replacement: Anatomic Total Shoulder Arthroplasty (replacement) or Reverse Total Shoulder Arthroplasty (replacement).

The components for a total shoulder arthroplasty consist of multiple parts: the humeral stem (short or standard) with a humeral head, or stemless with the humeral head, and a socket. The components may be metal or polyethylene material that have pegged or keeled designs with or without cement to anchor in place.

There are many conditions that may deteriorate the shoulder joint that leads to pain and decreased mobility. A detailed musculoskeletal examination should be performed to assess shoulder anatomy, shoulder tests, differential diagnosis, and pain patterns.

This guideline does not address partial shoulder arthroplasty (shoulder hemiarthroplasty), shoulder arthroscopy, or shoulder resurfacing, please see MCG criteria.

Definitions

"Ambulatory" is a stay in a facility for up to 23 hours.

"Anatomic Total Shoulder Arthroplasty (replacement)" is surgical reconstruction or replacement of the humeral head (ball) and the glenoid (socket) to make the glenohumeral joint.

"Arthropathy" is a term for disease of the joints, which can be caused by multiple factors including, but not limited to arthritis, infection, or blood disorders.

"Avascular necrosis" is spontaneous osteonecrosis (bone death) when there is alteration of blood supply to the bone. There are numerous causes for avascular necrosis, but in some cases the cause is unknown.

"Glenoid Version" evaluates glenoid bone stock loss and bone defects, which is crucial for surgical planning and expected outcomes. There are various methods to evaluate the glenoid version (e.g., anteversion, retroversion), but one common method is the Friedman method for which a line is drawn down the long axis of the scapula, from the tip of the medial border of the scapula to the center of the glenoid.

"Hemiarthroplasty" is surgical reconstruction or replacement of the affected humeral head without the replacement of the glenoid (socket). This is the preferred method for when the glenoid is intact and within normal condition.

"Osteoarthritis (degenerative joint disease)" is the most common form of arthritis and occurs when cartilage gradually wears down and affected bones no longer have the cushion of protective tissue. The primary symptoms are joint pain, stiffness and movement restriction.

"Reverse Total Shoulder Arthroplasty (replacement)" is surgical reconstruction or replacement of the humeral head (ball) and the glenoid (socket), but the ball and socket are reversed with the ball attached to the shoulder bone and the socket attached to the upper arm bone. This surgery technique is used when the rotator cuffs are completely torn or inadequate to allow for greater range of motion.

"Revision"of a total shoulder replacement is when surgery is needed to replace or reconstruct prior shoulder replacement due to failure, infection, instability or other indications.

"Rheumatoid arthritis" is an autoimmune disease causing chronic inflammation in joints and tissue. Over long periods of time, the inflammation can cause joint deformity, bone and cartilage erosion.

"Walch Classification of Glenoid Morphology" is a classification system of the morphologic features of the glenoid divided into subtypes. This classification groups the relationship of the humeral head and the glenoid for prognosis and preoperative planning.

Modified Walch Classification of Glenoid Morphology	
Types	Radiologic Findings
Type A: Centered or symmetric arthritis without posterior subluxation of the humeral head	A1- Minor central wear or erosion.
	A2 - (Bercik et al. elaborated on A2 subtype)- Severe or major central wear or erosion or presenting with a line connecting the anterior and posterior native glenoid rims that transects the humeral head.
Type B: Asymmetric arthritis with posterior subluxation of the humeral head	B1- No obvious glenoid erosion. Posterior joint space narrowing, subchondral sclerosis, and osteophytes present.
	B2- Apparent or obvious erosion of the posterior glenoid forming a biconcave appearance of the glenoid.
	B3- (Bercik et al. added additional subtype)- Monoconcave and worn preferentially in its posterior aspect, leading to pathologic retroversion of at least 15° or subluxation of 70%, or both
Type C:	C1 - Glenoid retroversion greater than 25° (dysplastic in origin) regardless of glenoid erosion or the location of the humeral head with regard to the glenoid C2- (Iannotti et al. added additional subtype) Dysplastic with high pathologic retroversion, high premorbid version, posterior bone loss, biconcave glenoid with posterior translation of the humeral head
Type D:	- (Bercik et al. added additional subtype) Glenoid anteversion or anterior humeral head subluxation

Clinical Indications

General Clinical Indications

(For partial shoulder arthroplasty, shoulder arthroscopy, or shoulder resurfacing, please see MCG criteria)
Total shoulder arthroplasty for a unilateral shoulder is considered medically necessary when ONE of the following criteria is met:

1. The member has an intact rotator cuff on the side of the shoulder planned for surgery; *and*
    a. The member has advanced joint disease as indicated by ALL of the following:

i. Radiologic (e.g., CT scan or MRI) or arthroscopic findings of advanced shoulder joint destruction of ONE of the following:
    1. Glenoid classification (Type B2 - Type D); *or*
    2. The humeral head shows degeneration, destruction, or any pathology requiring removal; *or*
    3. Symptomatic avascular necrosis or osteonecrosis of the humeral head with accompanying radiographic changes; *or*
    4. Symptomatic inflammatory joint disease (arthropathy) affecting both the humeral head and glenoid with joint space narrowing, bone-on-bone, with accompanying radiographic changes; *and*

b. Severe pain persisting in the affected shoulder that interferes with functional activity or age-appropriate activities for at least 3-months (e.g., cooking, employment, ability to sleep); *and*
c. There has been a failure to decrease pain or improve function after at least a 3-month trial of conservative treatment (non-surgical) which has included ALL of the following:
    i. Active and ongoing participation in a physical therapy (documentation required), or a well documented home exercise program under the supervision of a physical therapist or physician (e.g., strengthening program) or activity modification, unless poorly tolerated or contraindicated; *and*
    ii. Oral/topical medications (e.g., analgesics, NSAIDs), unless poorly tolerated or contraindicated; *and*
    iii. No intra-articular steroid injections to the shoulder within three months before the surgery date; *and*
d. If there is a separate request for the device, implant or prosthesis that will be inserted during surgery, it must be FDA approved (unless the member is enrolled in an approved clinical trial as defined by the plan benefit); *and*
e. No contraindication present or the request is not considered Experimental or Investigational, or Not Medically Necessary based on the indications listed below; *or*

2. Failure of previous surgical interventions such as ONE of the following:
    a. Failed hemi-arthroplasty; or
    b. Shoulder non-union or failure of previous shoulder fracture surgery; *or*
    c. Previous partial shoulder arthroplasty that needs conversion to total shoulder arthroplasty; *or*
3. Post-traumatic injury (e.g., fracture, infection) causing debilitating shoulder joint destruction affecting movement for activities of daily living, or causing pain and stiffness; *or*
4. Bone tumor or dysplasia involving the shoulder that requires excision and total reconstruction.

Reverse Total Shoulder Arthroplasty

Reverse total shoulder arthroplasty for a unilateral shoulder is considered medically necessary when the deltoid muscle is intact AND 90 degrees of passive shoulder motion AND ONE of the following criteria is met:

1. The member meets ONE of the criteria below:
    a. Failed rotator cuff repair, failed shoulder hemiarthroplasty, or failed shoulder arthroplasty; *or*
    b. Proximal humerus fracture with rotator cuff deficiency/insufficiency; *or*
    c. Complex fracture of humeral head; *or*
    d. Post-traumatic injury (e.g., fracture, infection) causing debilitating shoulder joint destruction affecting movement for activities of daily living, or causing pain and stiffness; *or*
    e. The member has a bone tumor or dysplasia resection or shoulder fracture that cannot be reconstructed with other shoulder techniques; *or*
2. The member mets ALL of the criteria below:
    a. The member has the following:
        i. Radiologic (e.g., CT scan or MRI) or arthroscopic findings of advanced shoulder joint destruction such as:
            1. Massive cuff tear arthropathy; *or*
            2. Rotator cuff deficiency due to arthropathy or malunion; *or*
            3. Pseudoparalysis (inability to actively elevate the arm) in the absence of a neurologic lesion and occurs secondary to irreparable rotator cuff tear; *or*
            4. The humeral head shows degeneration, destruction, or any pathology requiring removal; *or*
            5. Symptomatic avascular necrosis or osteonecrosis of the humeral head with accompanying radiographic changes; *or*
            6. Symptomatic inflammatory joint disease (arthropathy) affecting both the humeral head and glenoid with joint space narrowing, bone-on-bone, with accompanying radiographic changes; *and*
    b. Severe pain persisting in the affected shoulder that interferes with functional activity or age-appropriate activities for at least 3-months (e.g., cooking, employment, ability to sleep); *and*
    c. There has been a failure to decrease pain or improve function after at least a 3-month trial of conservative treatment (non-surgical) which has included ALL of the following:
        i. Active and ongoing participation in a physical therapy (documentation), or a well documented home exercise program under the supervision of a physical therapist or physician (e.g., strengthening program) or activity modification, unless poorly tolerated or contraindicated; *and*
        ii. Oral/topical medications (e.g., analgesics, NSAIDs), unless poorly tolerated or contraindicated; *and*
        iii. Therapeutic injections to the shoulder (unless contraindicated, including, but not limited to as irreparable rotator cuff tears, bone-on-bone, osteolytic cysts, osteophytes, and sclerosis) and not within 3-months before the surgery date; *and*

d. If there is a separate request for the device, implant or prosthesis that will be inserted during surgery, it must be FDA approved (unless the member is enrolled in an approved clinical trial as defined by the plan benefit); *and*
e. If the member is a smoker or nicotine product user, the member has stopped using within 4 weeks of surgery or has been provided a well documented education plan on options to quit such as referral to a cessation program, pharmacologic, and over the counter treatments have been documented; *and*
f. No contraindication present or the request is not considered Experimental or Investigational, or Not Medically Necessary based on the indications listed below.

Please Note: If the member is a smoker or nicotine product user, it is recommended the member has stopped using within 4 weeks of surgery or has been provided a well documented education plan on options to quit such as referral to a cessation program, pharmacologic, and over the counter treatments.

Simultaneous Shoulder Surgery
Total shoulder arthroplasty for simultaneous bilateral surgery is considered medically necessary if ALL of the following criteria are met:

1. Each shoulder meets medical necessity for criteria under General Clinical Indications; *and*
2. Meets the inpatient hospital Levels of Care criteria (see below).

Removal or Revision of Total Shoulder Arthroplasty
Removal (resection with subsequent reimplantation at a later time or permanent resection arthroplasty with no reimplantation planned) or Revision (members may require multi-staged surgeries to complete revision over time)
The removal or revision of a total shoulder prosthesis is considered medically necessary when ALL of the following criteria are met:

1. In the affected shoulder requested without history of prior infection, no current or ongoing shoulder infection (e.g., supporting labs and cultures, no longer on antibiotics, assessment by treating surgeon); *and*
2. One of the following:
    a. Bearing surface wear leading to symptomatic synovitis, destruction of local bone, or soft tissue reaction*; or*
    b. Infected shoulder prosthesis*; or*
    c. Periprosthetic infection*; or*
    d. Prosthesis/hardware failure, damage or fracture*; or*
    e. Loosening of prosthesis or components that is confirmed by imaging*; or*
    f. Periprosthetic shoulder fracture*; or*
    g. Recurrent instability or dislocation of the shoulder prosthetic*; or*
    h. The member has functional disability AND persistent pain for more than 6 months*; or*
    i. Significant arm discrepancy post TSA; *or*

3. If the member has an actively infected shoulder prosthesis or periprosthetic infection, one of the following criteria must be met:
    a. The member must first have completed medical management (e.g., antibiotics) or interventions such as washouts (including irrigation and debridement) prior to surgery day of inserted prosthesis, i.e., the member must clear out all infection (e.g., negative cultures) prior to the day of planned procedure whether one-stage or two-stage exchange)*; or*
    b. There is documentation for either planned medical or interventional management to address the source of infection prior to revision/replacement of the prosthesis*; or*
4. Additional staged surgery is needed as part of a multispecialty approach to any one of the conditions listed above. This could include, but is not limited to, additional joint washouts and the removal or replacement of hardware.

Levels of Care

Ambulatory Surgical Center, Outpatient Hospital

The following indications are appropriate for ambulatory surgical centers and outpatient hospital level of care:

- Unilateral TSA
- Select ambulatory centers with capability to perform bilateral TSA and each shoulder must meet medical necessity
- Staged TSA on both shoulders (request for each shoulder still needs to meet medical necessity and staggered typically between 30-90 days following the first total shoulder joint replacement).
- An additional day as an ambulatory or observation level of care might be needed for a safe transition to oral pain medication.

Inpatient Hospital

Inpatient hospital level of care for simultaneous bilateral total shoulder arthroplasty may be considered medically necessary if an ambulatory or outpatient hospital is unable to monitor the member's needs. Furthermore, each shoulder must meet medical necessity.

The member may also meet inpatient hospital level of care for unilateral or bilateral total shoulder replacement if ONE of the following are met:

- Non-elective surgery for unilateral or bilateral; *or*
- For members requesting unilateral or bilateral revision procedures that require an extended stay outside of the ambulatory or outpatient hospital timeframe, or are unable to be discharged and expected to be admitted/transferred to acute or subacute rehab facility (the member must also meet Oscar's utilization review criteria for the rehabilitation facility); *or*
- The member requires more prolonged postoperative treatment or management for unilateral or bilateral due to comorbidities which may include ANY of the following:
    - need for parenteral bridging anticoagulation

    - NYHA class III or IV heart failure
    - pulmonary fibrosis
    - pulmonary hypertension
    - history of thromboembolism
    - extensive edema
    - chronic systemic corticosteroid use
    - severely reduced renal function
    - Poorly controlled type 1 diabetes
    - recent history of falls
    - Significant dementia
    - BMI > 40
    - Age > 70 and an additional comorbidity as listed in this section
    - Significant movement abnormalities (eg, stroke, Parkinson disease, dependent functional status); *or*
- For a member to meet inpatient level of care for pain management after TSA surgery, the member must meet the criteria in MCG Pain Management GRG (PG-PM) criteria for unilateral or bilateral; *or*
- An inpatient admission for a unilateral or bilateral request may be considered medically necessary when the member meets MCG Ambulatory Surgery Exception Criteria (CG-AEC).

Extension Requests

The Plan considers extension requests for inpatient level of care medically necessary when the member continues to meet extension criteria in MCG Shoulder Arthroplasty for milestones of recovery, clinical status is improving during IP stay, and is not ready to be transitioned to an alternative or lower level of care. Extension requests should be based on medical records of progress.

Experimental or Investigational / Not Medically Necessary

The Plan considers the following conditions as contraindications:

- Active infection in the shoulder, unless surgery is for revision for TSA
- Active wound or skin infection at the planned shoulder joint for surgery
- Allergy to components of the implant
- Generalized infection, active illness or other acute medical management that would affect risk or morbidity
- Inadequate bone stock to support implantation of the prosthesis

The following indications are considered not medically necessary:

- Charcot joint of the shoulder
- Customized total or partial shoulder implant
- Deltoid deficiency
- Paralytic disorder of the shoulder

- Progressive neurologic disease affecting upper extremities or significant muscular atrophy of the arms
- Severe immunocompromised system
- Vascular insufficiency that would compromise recovery
- Any disease or process that rapidly destroys bone

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
Initial TSA CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))
C1776	Joint device (implantable)
Removal or Revision for TSA considered medically necessary if criteria are met:	
Code	*Description*
23333	Removal of foreign body, shoulder; deep (subfascial or intramuscular)
23334	Removal of prosthesis, includes debridement and synovectomy when performed; humeral or glenoid component
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (eg, total shoulder)
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component
C1776	Joint device (implantable) • Due to the broad nature of this code and lack of specificity in certain scenarios, clarification is provided below: • When this code is billed for customized shoulder implant, or devices not FDA approved, then it is considered NOT medically necessary.

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