

# Cohere Medicare Advantage Policy - Shoulder Arthroplasty

Clinical Guidelines for Medical Necessity Review

Version:

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#### **Guideline Information:**

**Specialty Area:** Disorders of the Musculoskeletal System

Guideline Name: Cohere Medicare Advantage Policy - Shoulder Arthroplasty

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**Type:**  $[\underline{\mathbf{X}}]$  Adult (18+ yo) |  $[\underline{\mathbf{X}}]$  Pediatric (0-17 yo)

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# **Medical Necessity Criteria**

#### Service: Shoulder Arthroplasty

## **Benefit Category**

Not applicable.

#### **Related CMS Documents**

Please refer to the <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.<sup>1</sup>

- Local Coverage Determination. Total Shoulder Arthroplasty. (L39956)
- Billing and Coding: Total Shoulder Arthroplasty. (A59878)

## **Recommended Clinical Approach**

Shoulder arthroplasty is a surgical intervention to reduce shoulder pain and restore function by replacing a damaged or diseased shoulder joint (i.e., the glenohumeral joint) with an artificial prosthesis.<sup>2</sup> It is considered the standard treatment for glenohumeral joint diseases including but not limited to osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis.<sup>1,2</sup> Total shoulder arthroplasty (TSA) is associated with improved pain and functional outcomes compared to hemiarthroplasty, which replaces only the ball of the ball and socket joint.<sup>4</sup> The American Academy of Orthopaedic Surgeons (AAOS) clinical practice guidelines indicate that anatomic TSA or reverse TSA is acceptable for treating glenohumeral joint osteoarthritis in patients with excessive glenoid bone loss, with or without rotator cuff muscular dysfunction.<sup>4</sup> Indications have recently expanded for reverse shoulder arthroplasty.<sup>4</sup> Revision surgery may be indicated for patients who had a joint arthroplasty and present with pain that is due to loosening, failure of the prosthesis, instability, or infection.<sup>4</sup>

#### **Evaluation of Clinical Benefits and Potential Harms**

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of shoulder arthroplasty procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals

reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment, such as disease progression, increased pain, decreased shoulder range of motion, and decreased ability to perform activities of daily living.<sup>1</sup>
- Surgical delay may result in increased healthcare utilization for emergency room visits or additional treatment, opioid dependence, and decreased quality of life.4-5
- Risks with inappropriate surgical procedures include infection, bleeding requiring a transfusion, injury to neurovascular structures, anesthetic risk, and need for repeat or additional procedures due to implant failure, periprosthetic fracture, and ongoing pain. The most common complications occurring after a reverse total shoulder arthroplasty are instability, periprosthetic fracture, infection, implant loosening, nerve injury, acromial or scapular spine fractures, hematoma, deltoid injury, rotator cuff tear, and venous thromboembolism. The most common complications occurring after an anatomic total shoulder arthroplasty are implant loosening, glenoid wear, instability, rotator cuff tear, periprosthetic fracture, nerve injury, infection, hematoma, deltoid injury, and venous thromboembolism.

The potential clinical benefits of using these criteria include:

- Improved patient outcomes by ensuring timely and appropriate access to shoulder arthroplasty procedures.
- Reduction in complications and adverse effects from unnecessary procedures. Given the complication rates of the reverse design and revision surgeries, the recommended treatment pathways should be followed. 4.9
- Appropriate management of orthopedic trauma, as treatment pathways, may differ depending on patient age and orthopedic injury type (e.g., arthritis versus fracture).
- Enhanced overall patient satisfaction, safety, and healthcare experience.<sup>1,4,5</sup> Appropriate use of these criteria will provide patients with better functional and pain outcomes across glenohumeral joint fractures and disease states.<sup>1,4</sup>

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

## **Medical Necessity Criteria**

#### **Indications**

- → **Shoulder arthroplasty** is considered medically appropriate if **ALL** of the following are **TRUE**<sup>1-16</sup>:
  - **♦ ANY** of the following:
    - Current nicotine user with no product use for 6 weeks and ANY of the following:
      - Negative lab test within 30 days; OR
      - Surgery is urgently required for progressive neurologic deficit; OR
    - No history of nicotine product use within the last 12 months;
       OR
    - No lifetime history of nicotine product use; AND
  - ◆ ANY of the following is TRUE:
    - The procedure is a hemiarthroplasty, and ANY of the following is TRUE:
      - Rotator cuff tear arthropathy; OR
      - o Malignancy of the glenohumeral joint; OR
      - Humeral head osteonecrosis with preserved glenoid;
         OR
      - Complex proximal humerus fracture<sup>12,16</sup>; OR
      - Primary osteoarthritis and ANY of the following is TRUE:
        - Glenoid bone stock is inadequate; OR

- ◆ The risk of glenoid loosening is high (i.e., young patients, heavy laborers)<sup>17</sup>; OR
- The procedure is a total shoulder arthroplasty, and ANY of the following is TRUE<sup>1</sup>:
  - Degenerative glenohumeral joint disease, including ALL of the following:
    - ANY of the following:
      - Osteoarthritis (OA), OR
      - Post-traumatic arthritis, OR
      - Rheumatoid arthritis (RA), OR
      - Osteonecrosis; AND
    - ◆ ANY of the following:
      - Documentation of moderate-to-severe chronic pain; OR
      - Chronic functional disability for a minimum of 12 weeks; AND
    - Documented radiographic evidence of the diagnosis (e.g., irregular joint surfaces, subchondral cysts, glenoid flattening or sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing, or avascular necrosis); AND
    - ◆ Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 12 weeks. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement (If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable<sup>18</sup>); OR
  - Treatment of acute proximal humerus fractures (PHFs) not amenable to conservative therapy or internal fixation; OR
  - Treatment of nonunion or malunion of the proximal humerus with radiographic evidence; OR

- Reconstruction following tumor resection of the glenohumeral joint, proximal humerus, or adjacent tissue; OR
- The procedure is a **reverse total shoulder arthroplasty**, and ANY of the following is TRUE:
  - ALL of the following:
    - The patient has disabling pain and loss of motion; AND
    - Radiographs are consistent with advanced osteoarthritis (e.g., destruction of shoulder joint, cystic changes, severe narrowing of joint space)4; AND
    - Failure of conservative management (e.g., rest, analgesics, supervised physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement (If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable (3); OR
  - Complex proximal humerus fractures 12,16; OR
  - Failed anatomic total shoulder arthroplasty<sup>1,9</sup>; **OR**
  - Failed shoulder hemiarthroplasty<sup>1,2</sup>; **OR**
  - Failed rotator cuff repair, deemed irreparable<sup>13</sup>; **OR**
  - Massive rotator cuff tears (MRCTs) when ALL the following are present<sup>13</sup>:
    - ◆ Evidence of MRCT by magnetic resonance imaging (MRI) or arthroscopy (e.g., tear size greater than 5 cm in an anterior-posterior or medial-lateral orientation)<sup>19</sup>; **AND**
    - Pseudo-paralysis (active elevation less than 90 degrees against gravity) 20,21; AND
    - Failure of conservative management (e.g., rest, analgesics, supervised physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 12 weeks. Documentation should include detailed

evidence of the measures taken, rather than solely a physician's statement (If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable<sup>18</sup>); **OR** 

- Proximal humerus fracture with ANY of the following 10:
  - Rotator cuff deficiency; OR
  - ◆ Malunion; OR
- o Reconstruction after tumor resection; OR
- Rheumatoid arthritis and **ALL** of the following 6.14:
  - ◆ Failure of conservative management (e.g., rest, analgesics, disease-modifying antirheumatic drugs [DMAR], physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; AND
  - Imaging confirms the presence of advanced rheumatoid arthritis; AND
  - Replacement is indicated due to ANY of the following:
    - Disabling pain; OR
    - Functional disability; OR
- Rotator cuff deficient arthropathy<sup>13</sup>; OR
- Rotator cuff tear arthropathy; OR
- Arthritis with posterior glenohumeral subluxation; OR
- Severe arthritis with glenoid bone loss, with or without glenohumeral instability; OR
- The procedure is a revision total shoulder arthroplasty, and ALL of the following are TRUE:
  - The patient has ANY of the following findings:
    - ◆ Pain; OR
    - Infection; OR
    - Instability; OR
    - ◆ Loosening of the prosthesis; **OR**
    - ◆ Failure of the prosthesis; **OR**
    - ◆ Periprosthetic fracture; **OR**
    - Glenoid erosion from a humeral prosthetic component of hemiarthroplasty; OR

- ◆ Implant fracture; OR
- ◆ Implant mechanical failure; OR
- Proximal migration of humeral head; AND
- The patient has ANY of the following advanced imaging or radiography findings:
  - ◆ Loosening of the prosthesis; **OR**
  - ◆ Failure of the prosthesis; **OR**
  - Normal (no findings) if infection or instability is present; OR
- The procedure is an **explant** for infection.

#### **Non-Indications**

- → Shoulder Arthroplasty is not considered appropriate if ANY of the following is TRUE<sup>15</sup>:
  - ◆ Active joint infection; **OR**
  - ◆ Systemic infection; OR
  - ◆ Neuropathic joint.

## **Level of Care Criteria**

Inpatient or Outpatient

## Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description	
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)	
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement [e.g., 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
23929	Unlisted procedure, shoulder

**Disclaimer:** G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

# **Medical Evidence**

Shoulder arthroplasty for the treatment of many conditions including osteoarthritis (OA), rheumatoid arthritis (RA), acute fracture (AF), and fracture sequelae (FS) has been shown to improve pain, function, and patient quality of life. Fevang, et al. reported that patients who underwent shoulder arthroplasty for OA or RA showed better results in pain, function, and quality of life compared with patients with AF or FS, though results were still favorable compared with preoperative measures across all diseases or fracture types. <sup>5</sup>

Centers for Medicare and Medicaid Services (CMS) as well as the American Academy of Orthopaedic Surgeons (AAOS) report that there is strong evidence to support the utilization of total shoulder arthroplasty (TSA) in patients with destructive or degenerative disease involving the shoulder joint when conservative therapy is unsuccessful or not appropriate; however, it is not without risks and possible complications. AAOS recommends a reasonable trial of conservative or nonoperative therapies before considering TSA, unless specific circumstances prohibit such an approach.

Harrison et al indicate that reverse total shoulder arthroplasty (RTSA) has relatively high complication (6–50%) and reoperation (5–24%) rates; however, this procedure can improve pain, function, and patient satisfaction when other surgical interventions are limited. The reverse design may address complications that arise following an anatomic TSA or hemiarthroplasty, such as glenoid component removal, rotator cuff failure or deficiency, or proximal humerus bone loss. In patients 65 years of age or older, rates of reverse shoulder arthroplasty (RSA) have increased while rates of hemiarthroplasty have decreased. Compared to other surgical procedures, RSA offers superior functional outcomes, range of motion, and patient satisfaction, and it is the preferred treatment for 3-part, 4-part, and head-splitting fractures of the proximal humerus in older adults.

Shoulder arthroplasty procedures for patients with rheumatoid arthritis (RA) have increased, and studies show no significant difference in adverse events between patients with or without RA. Inpatient versus outpatient total shoulder arthroplasty (TSA) are comparable in terms of complication rates, hospital readmissions, and emergency department visits, despite outpatient groups generally being younger and healthier. Although outpatient TSAs appear to be just as safe and effective, it is important to consider crucial factors such as age, comorbidities, and social support.

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# Clinical Guideline Revision History/Information

Original Date: May 31, 2024			
Review History			
Version 2	6/10/2024	422.101 Disclaimer added	
Version 3	3/20/2025	<ul> <li>Annual Review Change Summary</li> <li>Added new nicotine use standard language to the indications.</li> <li>TSA and RTSA indications updated in alignment with new LCD.         <ul> <li>The previously combined TSA/RTSA section was split into two standalone sections; TSA section replaced with language from L39956.</li> </ul> </li> <li>One final indication was added for procedure code regarding infection.</li> <li>Reviewed boolean logic.</li> <li>Literature review         <ul> <li>Clinical Approach, Benefits and Harms, and Medical Evidence sections updated with additional references in alignment with L39956.</li> </ul> </li> <li>Patient-Friendly Language         <ul> <li>Clinical Approach, Benefits and Harms sections updated.</li> </ul> </li> </ul>	