Cohere Medicare Advantage Policy - Shoulder Arthroplasty

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Shoulder Arthroplasty

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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Shoulder Arthroplasty

Benefit Category

Not applicable.

Recommended Clinical Approach

Shoulder arthroplasty is considered the standard treatment for diffuse glenohumeral joint osteoarthritis (GJO).[1] Total shoulder arthroplasty (TSA) is associated with improved pain and functional outcomes compared to hemiarthroplasty.[2] Guidelines published by the American Academy of Orthopaedic Surgeons (AAOS) indicate that anatomic TSA or reverse TSA is acceptable for treating GJO in patients with excessive glenoid bone loss, with or without rotator cuff dysfunction.[2] Indications have recently expanded for reverse shoulder arthroplasty. 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.

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:

- Inadequate management of severe shoulder conditions due to inappropriate denials. Untreated shoulder osteoarthritis will progress and can result in decreased shoulder range of motion, decreased ability to perform ADLs, increasing pain with potential opioid dependence.
- 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. Bohsali et al reported on complications associated with shoulder arthroplasty.[19] 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.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes by ensuring timely and appropriate access to shoulder arthroplasty procedures. Ristow et al reviewed outcomes for shoulder arthroplasty performed for avascular necrosis of the humeral head.[4] Patients who underwent a total shoulder arthroplasty had superior outcomes to those who had a hemiarthroplasty. Two patients out of 29 surgical cases had minor complications and no revision surgeries were necessary at 3.9 years follow up. Cvetanovich et al evaluated treatment options for an irreparable rotator cuff tear.[9] They noted that structural failure from attempting a repair of a massive rotator cuff occurs anywhere from 25-94% within 2 years of repair. They identified intermediate to advanced stage rotator cuff arthropathy, anterosuperior escape, pseudoparalysis and those older than age 65 years of age to have superior results with a reverse total shoulder arthroplasty. Haleem et al reviewed reported outcomes of primary total shoulder arthroplasty in patients with rheumatoid arthritis.[13] They report overall complication rate is 9% with revision rate of 8.4%.
- Reduction in complications and adverse effects from unnecessary procedures. Harrison et al evaluated revisions for primary total shoulder arthroplasty.[7] They noted revision of a primary shoulder arthroplasty to a reverse total shoulder arthroplasty resulted in poorer outcomes compared to primary reverse total shoulder arthroplasty.
- Enhanced overall patient satisfaction and healthcare experience.

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**[1-16]:
  - ◆ The patient has not smoked in greater than or equal to the last 6 weeks; **AND**
  - ◆ **ANY** of the following is **TRUE**:
    - The procedure is a hemiarthroplasty, and **ANY** of the following is **TRUE**:
      - Rotator cuff tear arthropathy; **OR**
      - Malignancy of the glenohumeral joint; **OR**
      - Humeral head osteonecrosis with preserved glenoid; **OR**
      - Complex proximal humerus fracture[15]; **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)[16]; **OR**
    - The procedure is a **total shoulder arthroplasty or 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)[2]; **AND**
        - ◆ Failure of conservative management (e.g., rest, analgesics, 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; **OR**
    - Humeral head osteonecrosis[4-5]; **OR**
- The procedure is a **reverse total shoulder arthroplasty**, and **ANY** of the following is **TRUE**:
    - Complex proximal humerus fractures[6,15]; **OR**
    - Failed shoulder arthroplasty[7]; **OR**
    - Failed shoulder hemiarthroplasty[7]; **OR**
    - Failed rotator cuff repair, deemed irreparable[1,8]; **OR**
    - Humeral head osteonecrosis; **OR**
    - Massive rotator cuff tear[9]; **OR**
    - Proximal humerus fracture with **ANY** of the following[10-11]:
        - ◆ Rotator cuff deficiency; **OR**
        - ◆ Malunion; **OR**
    - Reconstruction after tumor resection; **OR**
    - Rheumatoid arthritis and **ALL** of the following[12-13]:
        - ◆ 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[9]; **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).

Non-Indications

➔ **Shoulder Arthroplasty** is not considered appropriate if **ANY** of the following is **TRUE**[14]:

- Active joint infection; **OR**
- Systemic infection; **OR**
- Neuropathic joint; **OR**
- The patient has smoked within the last 6 weeks.[17-18]

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
20680	Removal of deep bone implant

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

Medical Evidence

Harrison et al. (2020) explore the indications and outcomes of revision reverse total shoulder arthroplasty. Rates of complications and reoperation are high however, revision of failed hemiarthroplasty or total shoulder arthroplasty increases patient outcomes. The authors note that many revision procedures involved a reverse design contributing to higher complications. Factors contributing to higher outcomes include the loosening of an existing component (cemented or uncemented), the presence of prior allograft composites, and deficiencies of bone or soft tissue due to implant wear or a previous procedure.[7]

Kelly and Myeroff (2020) analyze trends, outcomes, and principles of treatment options for proximal humerus fractures in patients over the age of 65. The review focuses on reverse shoulder arthroplasty (RSA). Rates of RSA have increased while rates of hemiarthroplasty have decreased. Older adults had lower revision rates with shoulder arthroplasty compared to hemiarthroplasty. Compared to other surgical procedures, RSA offers superior scores of functional outcomes, range of motion, and patient satisfaction.[10]

Leroux et al. (2018) note an increase in shoulder arthroplasty for patients with rheumatoid arthritis (RA) and rotator cuff disease. Data show a trend of performing shoulder arthroplasty for rotator cuff disease compared to repair. A total of 332,593 patients from 2002 to 2011 were included in the review; 17,883 patients (5.4%) were diagnosed with RA. Differences between adverse events among patients with RA and non-RA were not significant.[12]

References

1. Thomas M, Bidwai A, Rangan A, et al. Glenohumeral osteoarthritis. *Shoulder Elbow*. 2016;8(3):203-214. doi: 10.1177/1758573216644183. PMID: 27583021; PMCID: PMC4950285.
2. American Academy of Orthopaedic Surgeons (AAOS). Management of glenohumeral osteoarthritis: Evidence-based clinical practice guidelines. Published March 23, 2020. Accessed December 14, 2023. https://www.aaos.org/gjocpg.
3. Throckmorton TW. Shoulder and elbow arthroplasty. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopedics. 14th ed. Philadelphia, PA: Elsevier; 2021:600-655.e8.
4. Ristow JJ, Ellison CM, Mickschl DJ, et al. Outcomes of shoulder replacement in humeral head avascular necrosis. *J Shoulder Elbow Surg*. 2019 Jan;28(1):9-14. doi: 10.1016/j.jse.2018.06.031. PMID: 30224207.
5. Alkhateeb JM, Arafah MA, Tashkandi M, et al. Surgical treatment of humeral head avascular necrosis in patients with sickle cell disease: A systematic review. *JSES Int*. 2021 Mar 26;5(3):391-397. doi: 10.1016/j.jseint.2021.01.011. PMID: 34136845; PMCID: PMC8178624.
6. Sheibani-Rad S, Kuhn AW, Berrigan PS, et al. Reverse total shoulder arthroplasty versus hemiarthroplasty for the treatment of proximal humerus fractures: A model-based cost-effectiveness analysis. *J Am Acad Orthop Surg*. 2021 Dec 15;29(24):e1353-e1361. doi: 10.5435/JAAOS-D-21-00166. PMID: 34037546.
7. Harrison AK, Knudsen ML, Braman JP. Hemiarthroplasty and total shoulder arthroplasty conversion to reverse total shoulder arthroplasty. *Curr Rev Musculoskelet Med*. 2020 Aug;13(4):501-508. doi: 10.1007/s12178-020-09649-5. PMID: 32506261; PMCID: PMC7340699.
8. Willick SE, Sanders RK. Radiologic evaluation of the shoulder girdle. *Phys Med Rehabil Clin N Am.* 2004;15(2):373-406. doi: 10.1016/j.pmr.2004.01.004. PMID: 15145423.
9. Cvetanovich GL, Waterman BR, Verma NN, et al. Management of the irreparable rotator cuff tear. *J Am Acad Orthop Surg*. 2019 Dec 15;27(24):909-917. doi: 10.5435/JAAOS-D-18-00199. PMID: 31206436.
10. Kelly BJ, Myeroff CM. Reverse shoulder arthroplasty for proximal humerus fracture. *Curr Rev Musculoskelet Med*. 2020 Apr;13(2):186-199. doi: 10.1007/s12178-020-09597-0. PMID: 32281051; PMCID: PMC7174456.
11. Boin MA, Virk MS. CORR® synthesis: What is the role of reverse shoulder arthroplasty for the treatment of proximal humerus fractures in patients older than 65 years? *Clin Orthop Relat Res*. 2021 Nov 1;479(11):2421-2429. doi: 10.1097/CORR.0000000000001910. PMID: 34398855.
12. Leroux TS, Basques BA, Saltzman BM, et al. Shoulder arthroplasty in patients with rheumatoid arthritis: A population-based study examining

utilization, adverse events, length of stay, and cost. *Am J Orthop* (Belle Mead NJ). 2018 Jun;47(6). doi: 10.12788/ajo.2018.0046. PMID: 29979807.
13. Haleem A, Shanmugaraj A, Horner NS, et al. Anatomic total shoulder arthroplasty in rheumatoid arthritis: A systematic review. *Shoulder Elbow.* 2022 Apr;14(2):142-149. doi: 10.1177/1758573220954157. PMID: 35265179; PMCID: PMC8899319.
14. Hyun YS, Huri G, Garbis NG, et al. Uncommon indications for reverse total shoulder arthroplasty. *Clin Orthop Surg.* 2013 Dec;5(4):243-55. doi: 10.4055/cios.2013.5.4.243. PMID: 24340143; PMCID: PMC3858093.
15. Cadet ER, Ahmad CS. Hemiarthroplasty for three- and four-part proximal humerus fractures. *J Am Acad Orthop Surg*. 2012 Jan;20(1):17-27. doi: 10.5435/JAAOS-20-01-017. PMID: 22207515.
16. Saltzman BM, Leroux TS, Verma NN, et al. Glenohumeral osteoarthritis in the young patient. *J Am Acad Orthop Surg*. 2018 Sep 1;26(17):e361-e370. doi: 10.5435/JAAOS-D-16-00657. PMID: 30095514.
17. White CA, Patel AV, Wang KC, et al. The impact of tobacco use on clinical outcomes and long-term survivorship after anatomic total shoulder arthroplasty. *J Orthop*. 2023 Jan 7:36:99-105. doi: 10.1016/j.jor.2023.01.002. PMID: 36659901; PMCID: PMC9842961.
18. Khazzam M, Gee AO, Pearl M. Management of glenohumeral joint osteoarthritis. *J Am Acad Orthop Surg*. 2020 Oct 1;28(19):781-789. doi: 10.5435/JAAOS-D-20-00404. PMID: 32986386.
19. Bohsali, Kamal I. MD; Bois, Aaron J. MD, MSc, FRCSC; Wirth, Michael A. MD. Complications of Shoulder Arthroplasty. The Journal of Bone and Joint Surgery 99(3):p 256-269, February 1, 2017. | DOI: 10.2106/JBJS.16.00935

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