Surgery of the Shoulder

Policy Number: SURGERY 101.26
Effective Date: March 1, 2023

Instructions for Use

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Related Policies
None

Coverage Rationale

Surgery of the shoulder is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the:

- InterQual® CP: Procedures:
  - Arthroscopy or Arthroscopically Assisted Surgery, Shoulder
  - Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent)
  - Arthroscopy, Diagnostic, +/- Synovial Biopsy, Shoulder
  - Arthrotomy, Shoulder
  - Joint Replacement, Shoulder
  - Removal and Replacement, Total Joint Replacement (TJR), Shoulder
- InterQual® Client Defined, CP: Procedures, Revision, Total Joint Replacement (TJR), Shoulder (Custom) - UHG

Click here to view the InterQual® criteria.

Subacromial balloon spacers for the treatment of rotator cuff tears are unproven and not medically necessary due to insufficient evidence of efficacy.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Surgery of the Shoulder	
23470 23472 23473 23474	Medical notes documenting the following, when applicable: • Pertinent physical examination of the relevant joint • Severity of pain as documented on a validated pain scale • Functional disability(ies) as documented on a validated functional disability scale or described as

CPT Codes*	Required Clinical Information
Surgery of the Shoulder	
29805 29806 29807 29819 29821 29822 29823 29824 29825 29826 29827 29828	interfering with activities of daily living (preparing meals, dressing, driving, walking) • Upon request, we may require the specific diagnostic image(s) that documents the severity of joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) and that shows the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images ○ Note: When requested, diagnostic image(s) must be labeled with: ▪ The date taken ▪ Applicable case number obtained at time of notification, or member's name and ID number on the image(s) ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted • Advanced joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) • Reports of all recent imaging studies and applicable diagnostic tests, including the following, when applicable: ○ C-reactive protein (CRP) ○ Erythrocyte sedimentation rate (ESR) ○ Microbiological findings ○ Synovial fluid cytology • Condition requiring procedure, including relevant past history with dates • Physician's treatment plan, including pre-op discussion • Feasibility of arthroscopic approach • Co-morbid medical condition(s) • Therapies tried (including dates) and failed as documented by a lack of clinically significant improvement between at least two measurements concurrent to the therapy, on validated pain or functional disability scale(s) or quantifiable symptoms; these therapies could include: ○ Nonoperative Therapy (i.e., orthotics, medications/injections, physical therapy, other pain management procedures, etc.) ○ Surgery • Member has the ability to participate in post-surgical rehabilitation • For revision surgery, also include: ○ Details of complication ○ Complete (staged) surgical plan • If the location is being requested as an inpatient stay, provide medical notes to support at least one of the following: ○ Surgery is bilateral ○ Member has significant co-morbidities; include the list of comorbidities and current treatment ○ Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient

*For code descriptions, refer to the Applicable Codes section.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	Description
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
29805	Arthroscopy, shoulder, diagnostic, with or without synovial biopsy (separate procedure)
29806	Arthroscopy, shoulder, surgical; capsulorrhaphy
29807	Arthroscopy, shoulder, surgical; repair of slap lesion
29819	Arthroscopy, shoulder, surgical; with removal of loose body or foreign body
29820	Arthroscopy, shoulder, surgical; synovectomy, partial
29821	Arthroscopy, shoulder, surgical; synovectomy, complete
29822	Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])
29823	Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])
29824	Arthroscopy, shoulder, surgical; distal claviculectomy including distal articular surface (Mumford procedure)
29825	Arthroscopy, shoulder, surgical; with lysis and resection of adhesions, with or without manipulation
29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (i.e., arch) release, when performed (List separately in addition to code for primary procedure)
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair
29828	Arthroscopy, shoulder, surgical; biceps tenodesis
29999	Unlisted procedure, arthroscopy

Clinical Evidence

Subacromial Balloon Spacers

The INSpace™ Subacromial Tissue Spacer System (Stryker) is a new, minimally invasive, biodegradable balloon spacer for the treatment of massive, inoperable rotator cuff tears (MIRCTs). According to the manufacturer, it preserves musculoskeletal and bone tissues, does not require the use of an anchor, and does not require a permanent implant. It is used as a spacer to eliminate friction between the acromion and the humeral head or rotator cuff to restore shoulder function and reduce pain. It is designed to biodegrade over the course of twelve months. The current published literature is at high risk of bias due to small sample size, single-center focus, retrospective design, and lack of randomization, blinding, and control. Furthermore, studies include patients with varying rotator cuff tear sizes.

Verma et al. (2022-included in ECRI report below) conducted a multicenter, single blinded randomized controlled trial comparing the INSpace subacromial balloon spacer implant to partial repair of full thickness massive rotator cuff tears. 184 patients met the inclusion criteria: ≥ age 40, MRI imaging showing a full thickness massive rotator cuff tear measuring ≥ 5cm and involving ≥ 2 tendons within 9 months of study enrollment, functional deltoid muscle and preserved passive range of motion on physical examination, visual analog scale (VAS) score greater than 30mm and who underwent failed conservative

therapy for at least 4 months. Patients randomized to receive partial repair, underwent suture anchor repair of the posteriosuperior rotator cuff, and concomitant procedures were done on both groups. Follow up was completed at day 10, week 6 and 3,6,12 and 24 months, and included examination, review of complications, reoperations, medications and patient reported outcomes. Post operative rehabilitation was standardized for both groups. The primary outcome measure was the change from baseline to month 24 for the American Shoulder and Elbow Society (ASES) score, and secondary outcomes included the Western

Ontario Rotator Cuff (WORC) score, Constant-Murley shoulder score, visual analog scale (VAS) score, EuroQol-5 Dimensions-5 Level (EQ-5D-5L) quality-of-life (QOL) score, and active range of motion (ROM). The results showed that the InSpace demonstrated functional and patient reported outcomes comparable to partial repair at month 12, maintained to month 24 (2 year follow up is well beyond the anticipated degradation timeframe, indicating clinical improvement is sustained even after the implant has biodegraded). The InSpace group showed earlier recovery at week 6 as shown by improvements in the ASES, WORC, Constant-Murley scores and ROM. These results are limited by a lack of standardized concomitant procedures performed in both groups which may have impacted the results. Furthermore, the repair techniques, and the non-blinding of the examiners are a potential source of bias. Further studies addressing these limitations, as well as longer term follow up are warranted.

Metcalfe et al. (2022-included in ECRI report below) conducted a multi-center double-blind, group-sequential, adaptive randomized controlled trial on the effectiveness of the InSpace subacromial balloon spacer in patients with irreparable rotator cuff tears (the majority of which were ≥ 3cm) who underwent arthroscopic debridement of the subacromic space and biceps tenotomy plus insertion of INSpace balloon, compared to the same procedure without insertion of the INSpace device. 117 patients met the inclusion criteria that included adults with a rotator cuff tear with pain and loss of function that had failed conservative treatment and surgery was warranted. During standard shoulder arthroscopy, eligibility was verified, and participants were equally randomized to each group. The control group received surgery only by shoulder surgeons following a standardized technique. The intervention group received the same procedure followed by insertion of the INSpace balloon following the manufacturers recommended technique. The primary outcome was improvement in the Oxford Shoulder Score which is a 12-item patient reported measure of pain and function at 12 months. Secondary outcomes included the Constant Score, range of pain free ROM, the WORC index, EQ-5D-5L, change in symptoms, Participant Global Impression of Change, resource use, and adverse events. The results showed at 12 months, the primary outcome data were obtained from 114 of the original 117 participants and showed improvement in both groups compared to baseline, however the improvement was slightly greater in the control group. Secondary outcome results showed similar results. The authors concluded that this study demonstrates no meaningful benefit for the use of the INSpace device in addition to arthroscopic debridement. Limitations of this study include the fact that it did not address the use of the INSpace device alone, and COVID-19 restrictions limited the authors ability to complete data collection for objective measures, although the objective measures taken in the study correlated well with the primary outcome measures.

In a 2022 Hayes evolving evidence review, it was concluded that there is minimal levels of support for the use of the InSpace Biodegradable Subacromal Spacer for the treatment of irreparable rotator cuff tears. While a small evidence base is associated with improvement in patient centered outcomes, the very poor quality of available studies suggest that the potential clinical benefit should be regarded with caution.

A 2021 ECRI clinical evidence assessment, updated in 2022 entitled InSpace Subacromial Tissue Spacer System for Treating Massive Rotator Cuff Tears concluded that based on the results of one systematic review, two randomized controlled trials and four nonrandomized comparison studies, the InSpace is safe and improves function and quality of life (QOL) in patients with large to massive, irreparable rotator cuff tears (MRCT). However, RCTs included too few patients to form conclusions about its comparative effectiveness to arthroscopic repair or debridement, and none of the studies reported on outcomes longer than 2 years. Larger RCTs comparing InSpace as a standalone treatment and as adjunct treatment with other irreparable MRCT treatments and reporting on long-term patient-oriented outcomes are needed to validate findings and address evidence gaps. which may be partially addressed in ongoing clinical trials.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgeries of the shoulder are procedures and, therefore, not regulated by the FDA. However, devices and instruments used during the surgery may require FDA approval. See the following website for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 15, 2022)

On June 12, 2021, the FDA granted DeNovo classification of the InSpace™ Subacromial Tissue Spacer System (Stryker,Ortho-Space Ltd.). This Class II device is indicated for the treatment of massive, irreparable, full-thickness torn rotator cuff tendons due to trauma or degradation with mild to moderate gleno-humeral osteoarthritis in patients greater than or equal to 65 years of age whose clinical conditions would benefit from a treatment with a shorter surgical time compared to partial rotator cuff repair. See the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200039.pdf

References

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [*2022T0556X*]

ECRI Institute. Clinical Evidence Assessment. InSpace Subacromial Tissue Spacer System (Stryker Corp.) for Treating Massive Rotator Cuff Tears. September 2021; Updated July, 2022.

Hayes, Inc., Evolving Evidence Review. InSpace Biodegradable Subacromial Spacer (Stryker) for Irreparable Rotator Cuff Tears. Lansdale PA: Hayes, Inc., March 2022.

Metcalfe A, Parsons H, Parsons N, et al; START:REACTS team. Subacromial balloon spacer for irreparable rotator cuff tears of the shoulder (START:REACTS): a group-sequential, double-blind, multicentre randomised controlled trial. Lancet. 2022 May 21;399(10339):1954-1963.

Verma N, Srikumaran U, Roden CM, et al; on behalf of the SPACE GROUP. InSpace implant compared with partial repair for the treatment of full-thickness massive rotator cuff tears: a multicenter, single-blinded, randomized controlled trial. J Bone Joint Surg Am. 2022 Jul 20;104(14):1250-1262.

Policy History/Revision Information

Date	Summary of Changes

03/01/2023	**Coverage Rationale**
	• Revised language pertaining to medical necessity clinical coverage criteria:
	  ○ Added reference to the InterQual® CP: Procedures, Removal and Replacement, Total Joint Replacement (TJR), Shoulder
	  ○ Replaced reference to the "InterQual® Client Defined, CP: Procedures, *Removal and Replacement*, Total Joint Replacement (TJR), Shoulder (Custom) - UHG" with "InterQual® Client Defined, CP: Procedures, *Revision*, Total Joint Replacement (TJR), Shoulder (Custom) - UHG"
	• Added language to indicate subacromial balloon spacers for the treatment of rotator cuff tears are unproven and not medically necessary due to insufficient evidence of efficacy
	Applicable Codes
	• Added CPT code 29999
	Supporting Information
	• Added *Clinical Evidence* section
	• Updated *FDA* and *References* sections to reflect the most current information
	• Removed *Definitions* section
	• Archived previous policy version SURGERY 101.25

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates.

UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.